The EPA laboratory safety, health and environmental (SHE) programs discussed in this chapter, span three major areas: administrative programs, safety and health programs, and environmental programs. These programs are intended to cover all elements necessary to provide a safe workplace for EPA employees, contractors, and the visitors, as well as to ensure that the environment is not adversely effected by the laboratory operations.

These chapters on EPA laboratory SHE programs are as follows:

Chapter	Topic
C2	Medical Surveillance Program
C3	SHE Training
C4	Chemical Hygiene Program
C5	Industrial Hygiene Program
C6	Radiation Safety Program
C7	Biosafety Program
C8	Ergonomics Program
C9	Pollution Prevention Program
C10	Air Quality Program
C11	EPCRA Program
C12	Wastewater Program

Chapter	Topic
C13	SPCC Program
C14	Waste Management Program
C15	TSCA Program
C16	UST Program

1.0 Introduction

A medical surveillance program serves to assess critical variables in an employee's health before, during, and after employment. Medical surveillance involves monitoring the health of employees, with particular emphasis on the adverse health effects that may be caused by exposure to chemical, physical, or biological agents in the workplace.

The fundamental purpose of medical surveillance is to evaluate the pathological effects of past exposure. This information is used to evaluate the level of morbidity and mortality attributed to the development of disease in the monitored population. Medical monitoring focuses on establishing the probability of a disease being present, rather than on confirming the diagnosis of the disease. Thus, the tests that are conducted in a medical surveillance program tend to be simpler, less expensive, less invasive, and more comfortable than diagnostic test procedures.

This chapter presents minimum requirements for, and addresses specific components of, a medical surveillance program as required by the U.S. Occupational Safety and Health Administration (OSHA). It also discusses biological monitoring considerations and program implementation issues.

EPA Program Requirements

The EPA medical surveillance program was developed to ensure that, to the best extent feasible, EPA employees subject to extraordinary physical demands or hazardous exposures have not suffered adverse health effects. The requirements set forth are based on EPA Order 1460.1, "EPA Occupational Medical Surveillance Program Document."

Program Administration

To effectively manage the laboratory medical surveillance program, responsibilities should be assigned for:

- Designing a medical program appropriate for potential exposures
- Determining which employees will be included in the program
- Ensuring that employees in the program receive medical examinations when assigned to a task where exposures to hazardous agents could occur
- Providing follow-up care, including annual examinations
- Maintaining medical records

2.0 Scope and Application

Minimum requirements for occupational medical surveillance programs include:

- Medical examinations for personnel who will be working with potentially hazardous agents, both at the time they are assigned to the program and before they are exposed
- Medical examinations on an annual basis, and upon termination of an employee's participation in the research
- Medical approval by a physician for the use of negative-pressure respirators

The scope of the medical examination must be specified in the laboratory's safety and health plan and/or chemical hygiene plan.

These minimum requirements also specify that laboratories comply with applicable federal, state, and local statutes regarding medical surveillance.

The recommended participant selection criteria for the EPA medical surveillance program is based on the employee's position description and regularly assigned tasks and duties. An employee should be selected for the medical surveillance program if their position description, or regularly assigned tasks and duties, meet any of the following criteria:

- Presents a routine or periodic exposure to hazardous chemical, physical, or biological agents
- Requires the use of animals or human pathogenic materials
- Requires the use of respiratory protection
- Involves physically demanding work, such as routine heavy lifting and carrying
- Involves emergency response activities
- Involves an activity or known exposure that is currently regulated by OSHA, and the applicable regulation mandates medical surveillance

The EPA laboratory shall provide all required medical surveillance at no cost to affected staff, without loss of pay, and at a reasonable time and place.

3.0 Types of Examinations

A medical surveillance program should be developed for each EPA laboratory based on the specific needs and potential exposures of employees. The program should be designed by an experienced occupational health physician or other qualified occupational health consultant in conjunction with the laboratory's SHEMP Manager. The director of the facility's medical surveillance program and the physician performing the examinations should be Board-certified in occupational medicine.

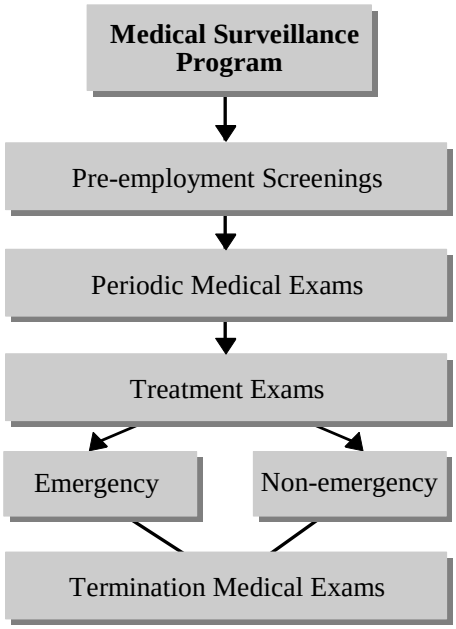
Alternately, the director could be a medical doctor who has had extensive experience managing occupational health services.

Although medical surveillance requirements may vary from laboratory to laboratory, a medical program should provide the following types of surveillance:

- Pre-employment screening
- Periodic medical examinations
- Termination examinations
- Treatment examinations (e.g., emergency and non-emergency)
- Recordkeeping

Each of these are discussed in the following sections and shown in Figure C2-1.

Figure C2-1: Components of a Medical Surveillance Program



3.1 Pre-employment Screening

Pre-employment screening has two major functions:

- Determining an individual's fitness for their work assignment
- Providing baseline data for comparison with future medical data

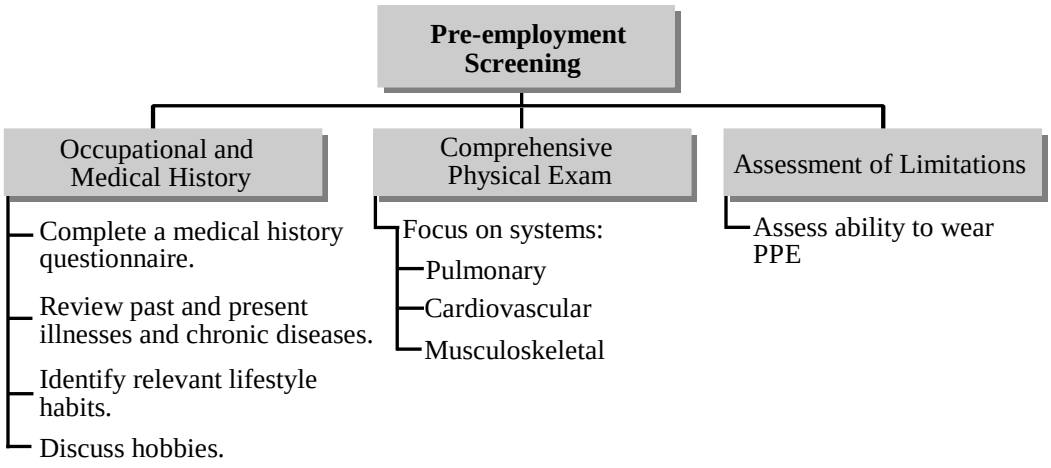
To ensure that prospective employees are able to meet work requirements, the pre-employment screening should focus on the areas as shown in Figure C2-2.

Pre-employment screening may be used to establish baseline data that will verify the effectiveness of protective measures and determine if exposures have adversely affected the worker. In this case, examinations may include both medical screening tests and biological monitoring. Where applicable (e.g., work with infectious agents), pre-employment blood specimens and serum may be collected and frozen for later testing. Baseline monitoring may be particularly relevant if there is a likelihood of potential exposure to a particular agent.

3.2 Periodic Medical Examinations

Periodic medical examinations should be developed and used in conjunction with pre-employment screening to track biological trends that may signal adverse health effects. Yearly medical examinations are required at EPA laboratories. More frequent examinations may be necessary, depending on the extent of potential or actual exposure, the type of chemicals involved, the duration of the work assignment, and the individual employee's profile.

Figure C2-2: Components of Pre-employment Screening



Periodic medical examinations should include the components as shown in Figure C2-3.

3.3 Termination Examinations

At the end of their employment, a medical examination must be given to all employees who are enrolled in a medical surveillance program. This examination may be limited to obtaining medical history of the period since the last full examination (e.g., medical history, physical examination, and laboratory tests) if all of the following conditions are met:

- The last complete medical examination was within the last six months.
- No exposure occurred since the last examination.
- No symptoms associated with exposure occurred since the last examination.

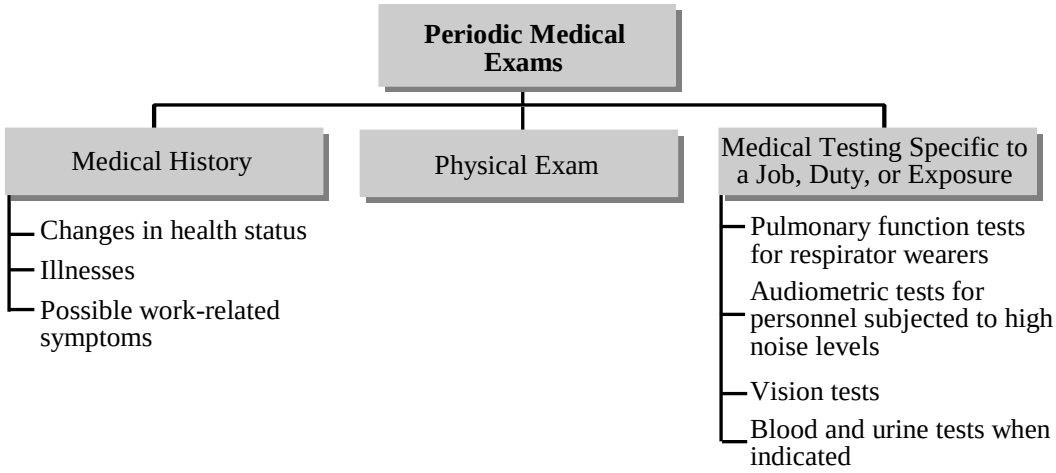
3.4 Treatment Examinations

Provisions for emergency and non-emergency treatment should be made at each EPA laboratory. Preplanning is vital. When developing emergency medical plans, procedures, and lists of required supplies and equipment, the range of actual and potential hazards specific to the facility should be considered, including chemical, physical, and biological hazards. In addition to laboratory employees, other personnel, such as contractors and visitors, may require medical treatment.

3.4.1 Emergency Treatment

EPA laboratories that do not have a nurse or physician on-site, or where additional first-aid support is deemed necessary, should establish a first-aid team. In addition to receiving basic first-aid training, it its recommended that the team members become qualified in cardiopulmonary resuscitation (CPR).

Figure C2-3: Components of Periodic Medical Exams



EPA laboratories should establish a first-aid station(s) that permits stabilization of patients requiring off-site treatment and general first aid (e.g., minor cuts, sprains, and abrasions). It should include a standard first-aid kit, or equivalent supplies, as well as additional items such as stretchers, potable water, ice, emergency eyewash, safety shower, and fire-extinguishing blankets. First-aid supplies should be approved by the consulting physician.

Plans should be made in advance for transportation to, and treatment at, a nearby medical facility. Ambulance and hospital personnel should be informed of hazards at the laboratory that could result in the need for medical treatment. The names and telephone numbers of the emergency service providers should be conspicuously posted (e.g., nurse/physician, ambulance, medical facility, fire/police, and poison-control hotline).

In addition, laboratory personnel have the right to obtain medical exams in the event of a spill or other exposures.

3.4.2 Non-emergency Treatment

Medical examinations and consultations shall be performed by, or under the direct supervision of, the employee's physician and without cost or loss of pay to the employee. All medical examinations shall be provided to EPA laboratory employees at a reasonable time and place under the following circumstances:

- Whenever an employee develops signs or symptoms associated with possible exposure to hazardous chemicals handled in the laboratory

- Where exposure monitoring reveals an exposure level routinely above the action level or—in the absence of an action level—the permissible exposure limit for an OSHA-regulated substance for which there are exposure monitoring and medical surveillance

requirements (other medical surveillance requirements of relevant standards shall also be observed)

- Following a medical consultation during which the physician determines the need for a medical examination; for example, in response to an event such as a spill, leak, explosion, or other occurrence causing likely exposure

For all medical consultations and examinations, EPA laboratories shall provide the following information to the physician:

- The identity of the hazardous chemicals(s) to which the employee may have been exposed

- A description of the conditions under which the exposure occurred, including quantitative exposure data, if available

- A description of the signs and symptoms of exposure that the employee has experienced, if any

For all medical consultations and examinations performed in accordance with the OSHA Laboratory Standard, the examining physician shall provide to the laboratory a written opinion that includes the following:

- Recommendation for further follow-up

- Results of the medical examination and any associated tests

- Any medical condition that may be revealed in the course of the examination and that may place the employee at increased risk of exposure to a hazardous chemical found in the laboratory

- A statement that the physician has informed the employee of the results of the consultation or medical examination and any medical condition that may require further examination or treatment

The physician's written opinion to the employer shall not reveal specific findings or any diagnosis unrelated to occupational exposure even if he chooses to relay them to the employee.

All medical records must be maintained in accordance with 29 CFR 1910.1020.

4.0 Specific Surveillance Requirements

In a laboratory, there are certain hazardous materials and operations that have additional medical surveillance requirements. Table C2-1 provides a summary of OSHA standards that have specific medical surveillance requirements. The following sections describe some of these surveillance requirements for common hazardous materials and operations. Figure C2-4 summarizes the common materials and operations discussed in this section.

4.1 Bloodborne Pathogens

EPA laboratories must provide all employees who are occupationally exposed to bloodborne pathogens (BBP) and other

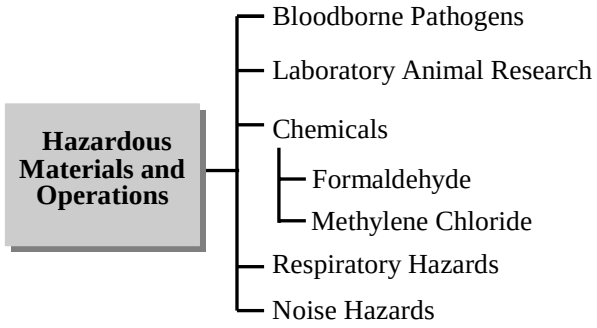
Table C2-1: OSHA Standards with Specific Medical Surveillance Requirements

Standard	Citation
Acrylonitrile	29 CFR 1910.1045
Arsenic (inorganic)	29 CFR 1910.1018
Asbestos	29 CFR 1910.1001
Benzene	29 CFR 1910.1028
Bloodborne pathogens	29 CFR 1910.1030
1,3-Butadiene	29 CFR 1910.1051
Cadmium	29 CFR 1910.1027
Carcinogens (specific chemicals)	29 CFR 1910.1003
1,2-dibromo-3-chloropropane (DBCP)	29 CFR 1910.1044
Ethylene oxide	29 CFR 1910.1047
Formaldehyde	29 CFR 1910.1048
Laboratory	29 CFR 1910.1450
Lead	29 CFR 1910.1025
Methylene chloride	29 CFR 1910.1052
Methylenedianiline (MDA)	29 CFR 1910.1050
Occupational noise exposure	29 CFR 1910.95
Respiratory protection	29 CFR 1910.134
Vinyl chloride	29 CFR 1910.1017

potentially infectious materials (OPIM) with medical surveillance per the requirements of OSHA's Bloodborne Pathogens Standard. Medical surveillance required under the standard includes administering the Hepatitis B vaccine and conducting post-exposure evaluation and follow-up.

Refer to Chapter C7 of this manual for additional information on the components of a biosafety program.

Figure C2-4: Hazardous Materials and Operations with Specific Medical Surveillance Requirements



4.1.1 Hepatitis B Vaccination

A vaccine is available to protect personnel against infection from Hepatitis B. OSHA requires that employers make this vaccine available free of charge to all personnel with potential occupational exposure to blood or OPIM. Vaccination programs must be administered in accordance with the recommendations of the U.S. Public Health Service and under the supervision of a licensed physician or healthcare professional.

The vaccine is noninfectious, and will not prevent Hepatitis A, C, or E. The vaccine is typically administered as three injections in the arm over six months. The second injection is given one month after the first, and the third is given at six months. To ensure adequate immunity, it is important for employees to receive all three injections.

There are special considerations for employees who provide first aid for incidents occurring in the workplace, since the risk of exposure for these employees is considered to be low. According to OSHA, these responders only need to be offered the Hepatitis B vaccine within 24 hours of exposure to blood or OPIM. This exemption only applies to employees whose routine work assignments do not include administering first aid. In addition, the employer must meet other provisions of the OSHA standard.

In both cases, employees may decline the Hepatitis B vaccine, and may request to be vaccinated at a later date. However, employees who choose not to receive the vaccine must sign a mandatory declination statement.

4.1.2 Post-exposure Evaluation and Follow-up

An exposure incident is defined as blood or OPIM contact with eyes, mouth, mucous membrane, or broken skin, resulting from the performance of an employee's duties. Immediately following an exposure incident, employees are required to receive confidential post-exposure medical evaluation and follow-up.

The medical evaluation and follow-up involves:

- Evaluating the incident and documenting the route of exposure, HBV and HIV status of the source (if known), and the circumstances of exposure
- Collecting and testing the exposed employee's blood to determine HIV and HBV status
- Collecting and testing the source individual's blood if HIV and HBV status are not already known
- Informing the employee of test results
- Providing counseling to the employee
- Administering post-exposure prophylaxis (e.g., Hepatitis B immunoglobulin) when medically indicated
- Evaluating any reported illness related to the exposure incident
- Offering additional HIV testing to the affected employee six weeks after exposure and periodically thereafter

4.2 Laboratory Animal Research

Allergies and musculoskeletal injuries are the primary health risks to individuals using and caring for laboratory animals. Allergies are a significant problem, but they can be reduced by using protective equipment. Musculoskeletal injuries can be minimized by good laboratory planning, use of transport equipment (e.g., carts), and training in lifting techniques and equipment use.

Infectious diseases may constitute a significant risk depending on the species and health status of animals involved, and the level to which animal care personnel are exposed to viral infections (e.g., rabies from random source dogs and lymphocytic choriomeningitis from hampsters and mice).

Cell cultures, animal tissues, and excreta can also serve as sources of infectious disease. Careful monitoring and quarantine of any animals with potential viral or bacterial infections is a critical part of quality assurance in animal care programs. Particular care must be taken in laboratories handling nonhuman primates (NHPs), because these animals are most prone to carry infections that are known to cause serious disease in humans (e.g., Herpes B, encephalitis, and tuberculosis). Routine periodic mycobacterial skin testing of employees and associated NHPs is essential.

Animal bites and scratches are hazards common to animal care personnel. All cases should be documented by completing an incident report and recording it in an incident log. Tetanus immunizations should be routinely administered every 10 years and at the time of a potential exposure.

Laboratory employees working with *BacillusCalmette-Guerin* (BCG)-injected animals will be provided tuberculin skin testing during employment examinations and annually thereafter.

Employees working with NHPs will receive the following:

- Blood serum tests wherein the serum is sampled, frozen, and stored during pre-employment examinations, annually, and on exiting
- Tuberculin skin testing with a purified protein derivative during pre-employment examinations and every six months
- Chest x-ray for those with a history of positive reaction to tuberculin skin testing
- Hepatitis B vaccination (optional)
- Stool samples to check for salmonella, shigella, and campylobacter

Protection against Herpes B virus should be provided in the event of a monkey bite or scratch.

4.3 Chemical-Specific Surveillance

As required by the OSHA Laboratory Standard, all laboratory employees working with hazardous chemicals shall have access to medical attention, including any follow-up examinations that the examining physician determines to be necessary.

Two chemicals commonly used in EPA laboratories with medical monitoring requirements are formaldehyde and methylene chloride. Their requirements are outlined in the following sections. For other chemical-specific medical surveillance requirements, refer to the OSHA standard for that chemical.

4.3.1 Formaldehyde

The use of formaldehyde in histology, pathology, and anatomy laboratories is covered by OSHA's Formaldehyde Standard in 29 CFR 1910.1048. For these operations, EPA laboratories must institute a medical surveillance program for all employees who are:

- Exposed to formaldehyde at concentrations at or above an 8-hour time-weighted average (TWA) or above the short-term exposure limit (STEL)
- Developing signs and symptoms of overexposure to formaldehyde
- Exposed to formaldehyde in an emergency

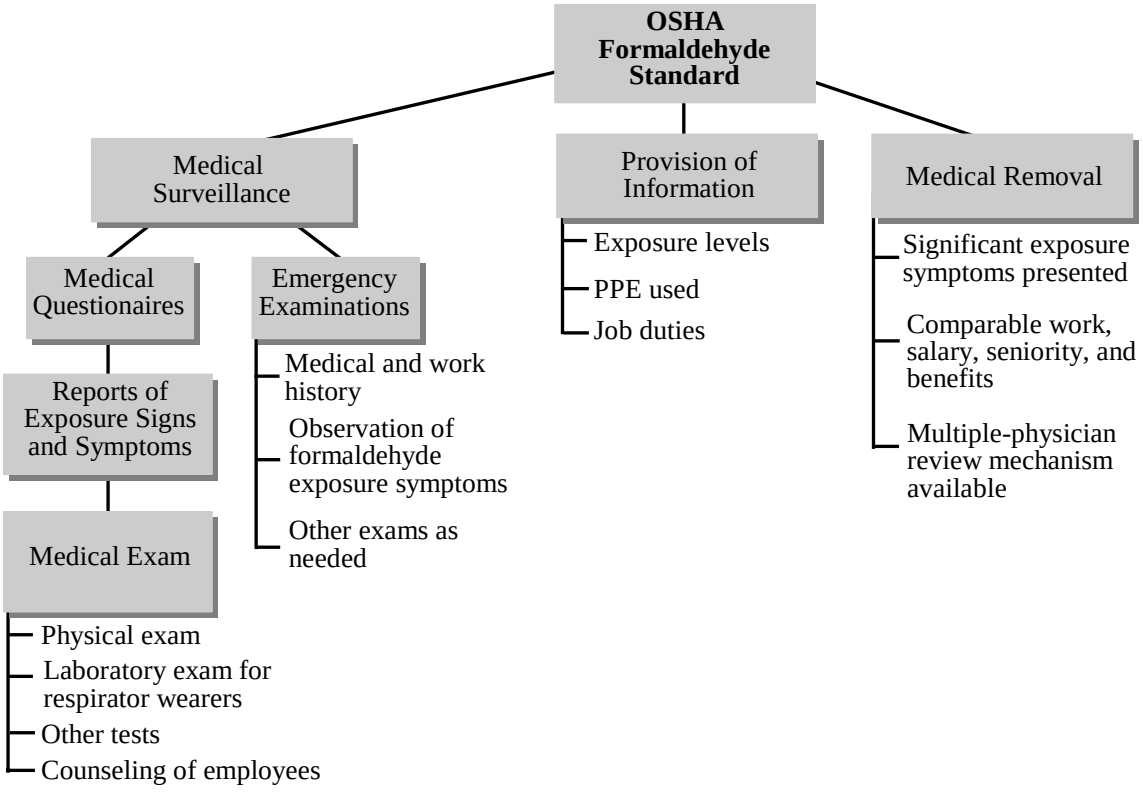
The OSHA standard presents information pertaining to formaldehyde medical surveillance, emergency examinations, provision of information by an employer to the physician, and medical removal due to the significant exposure symptoms. These components are summarized in Figure C2-5 and are discussed in the following sections.

Medical Surveillance

Unlike some other specific standards, the formaldehyde standard does not require periodic medical examinations for employees exposed at or above the action level. Instead, medical surveillance is performed by completing medical questionnaires, submitting reports of exposure signs and symptoms, and obtaining medical examinations when necessary as detailed below.

Medical surveillance for employees exposed at or above the action level or STEL, and who experience signs or symptoms indicating probable exposure, must include the following:

Figure C2-5: Components of the OSHA Formaldehyde Standard



*Completing Medical Questionnaires.*The medical questionnaire, such as the one included in Appendix D of the OSHA Formaldehyde Standard, is designed to elicit information on:

- Work history
- Smoking history, evidence of eye, nose, and throat irritation
- Chronic airway problems or hyperactive airway disease
- Allergic skin conditions or dermatitis
- Upper and lower respiratory problems

Submitting Reports of Exposure Signs and Symptoms. In conjunction with the medical questionnaire, employees should submit reports of any exposure signs and symptoms to medical staff.

If an employee reports signs or symptoms, and the physician determines that a medical examination is not immediately necessary, a two-week observation period then begins. The purpose of this observation period is to provide an opportunity to evaluate the problem and to treat the condition or causative factors in the workplace. This provision is supported by the fact that many formaldehyde-induced signs and symptoms often resolve themselves within a few hours or a few days. Also, the observation period will allow the laboratory to determine whether signs or symptoms subside spontaneously, with minimal treatment, or whether improvements to working conditions can be made to alleviate the exposure, and the resulting condition, without unnecessary expenditure. If the signs or symptoms have not subsided or been remedied by the end of the two-week observation period, the affected employee must be examined by the physician. If the signs and symptoms worsen during the two-week period, the employee must be examined by the physician as soon as this fact is determined.

Obtaining Medical Examinations. Based on evaluation of the medical questionnaire, a physician determines whether a medical examination is necessary for employees who are not required to wear respirators to reduce their exposure to formaldehyde.

Medical examinations shall be given to any employee who the physician feels may be at increased risk from exposure to formaldehyde, based on the information in the medical questionnaire. All employees required to wear a respirator to reduce exposure to formaldehyde must obtain a medical exam at least annually. The medical examination shall include:

- A physical examination with emphasis on evidence of irritation or sensitization of the skin and respiratory systems, shortness of breath, or irritation of the eyes
- Laboratory examinations for respirator wearers consisting of baseline and annual pulmonary function tests
- Any other test that the examining physician deems necessary to complete the written opinion
- Counseling of employees having medical conditions that would be directly or indirectly aggravated by exposure to formaldehyde, or result in an increased risk of impairment to their health

Emergency Examinations. For employees exposed to formaldehyde in an emergency, examinations must be made as soon as possible following the emergency. These examinations shall include a medical and work history with emphasis on any evidence of upper or lower respiratory problems, allergic conditions, skin reaction, or hypersensitivity, and any evidence of eye, nose, or throat irritation. Other examinations shall consist of those elements considered appropriate by the examining physician.

Provision of Information

OSHA has set specific requirements concerning the information that must be provided by the employer to the physician. This information includes exposure levels in the employee's job assignment, any personal protective equipment used by the employee, and a description of the employee's job duties as they relate to the exposure. OSHA has established specific requirements concerning the written opinion that the physician must provide for each examination required under the formaldehyde standard.

Medical Removal Provisions

The OSHA Formaldehyde Standard includes medical removal provisions that apply when an employee reports significant irritation of the mucosa of the eyes or upper airways, respiratory sensitization, dermal irritation, or dermal sensitization attributed to workplace formaldehyde exposure.

In the case of dermal irritation and dermal sensitization in the absence of other symptoms, the medical removal provisions do not apply when the percentage of formaldehyde in the product suspected of causing the dermal condition is below 0.05 percent. This restriction was established based on evidence that only those products with higher concentrations have clearly been associated with dermal irritation or sensitization.

In the event of a recommendation of removal by the examining physician, the affected employee must be removed from the current formaldehyde exposure and, if possible, transferred to work having no (or significantly less) exposure to formaldehyde. OSHA requires that the employee be transferred to a position involving comparable work for which the employee is qualified. If there is no such work available, the employer is required to maintain the employee's current earnings, seniority, and other benefits until:

- Such work becomes available.
- The employee is determined to be unable to return to the workplace because of formaldehyde exposure.
- The employee is determined to be able to return to the original job status; or for six months, whichever comes first.

Within six months of the medical removal, the physician must then decide whether the employee can be returned to his or her original job status, or if the removal is to be permanent.

OSHA provides for a multiple-physician review mechanism in the Formaldehyde Standard to ensure successful operation of the program. Multiple-physician review provides employees with an opportunity for a second medical opinion when a worker questions the recommendations from a physician chosen by the employer.

This provision serves to ensure employee confidence in the soundness of any medical determinations that may significantly affect their health or their job status.

4.3.2 Methylene Chloride

The EPA laboratory shall make medical surveillance available for staff who are, or may be, exposed to methylene chloride as follows:

- At or above the action level on 30 or more days per year, or above the 8-hour TWA permissible exposure limit (PEL) or the STEL on 10 or more days per year
- Above the 8-hour TWA PEL or STEL for any time period where an employee has been identified by a physician or other licensed health care professional as being at risk from cardiac disease or from some other serious methylene chloride–related health condition and such employee requests inclusion in the medical surveillance program
- In the event of an emergency

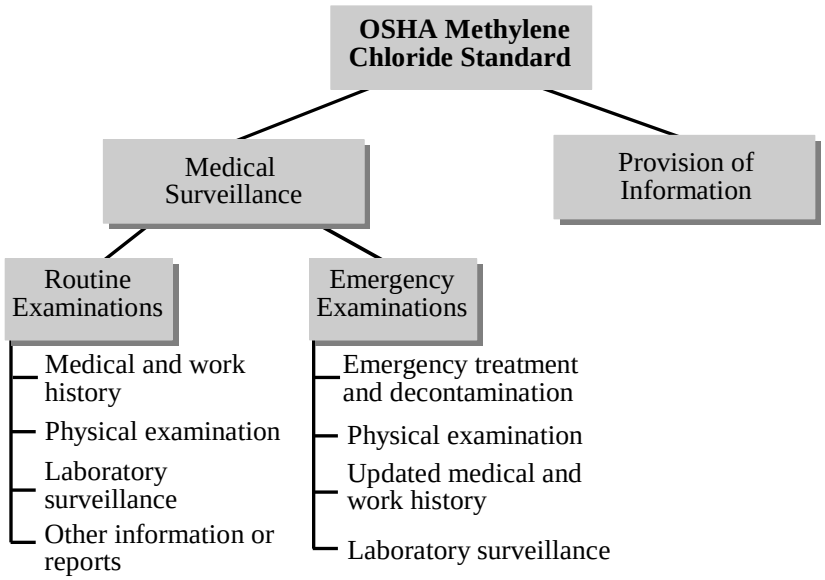
In addition, the EPA laboratory shall provide all required medical surveillance at no cost to affected staff, without loss of pay, and at a reasonable time and place. All medical surveillance procedures are to be performed by a physician or other licensed health care professional. The frequency of medical surveillance provided to staff should be as presented in Table C2-2.

The standard presents information on medical surveillance and provision of information, as shown in Figure C2-6 and discussed in the following sections.

Table C2-2: Frequency of Medical Surveillance for Methylene Chloride

Frequency of Surveillance	Description
Initial	Initial medical surveillance must be provided under the schedule, or before the time of initial assignment of the employee, whichever is later.
Periodic	Update of the medical and work history for each affected employee must be performed annually. Periodic physical examinations, including appropriate laboratory surveillance, should be provided, as follows: • For employees 45 years of age or older, within 12 months of the initial surveillance or any subsequent medical surveillance • For employees younger than 45 years of age, within 36 months of the initial surveillance or any subsequent medical surveillance
Termination	Upon termination of employment or reassignment to an area where exposure to methylene chloride is consistently at or below the action level and STEL, medical surveillance shall be made available if six months or more have elapsed since the last medical surveillance.
Additional	Additional medical surveillance should be provided at frequencies other than those listed above when recommended in a written medical opinion.

Figure C2-6: OSHA Methylene Chloride Standard Medical Surveillance Requirements



Routine Examinations
The content of medical surveillance performed on staff occupationally exposed to methylene chloride should include the information in the following sections.

Medical and Work History. The comprehensive medical and work history shall include identification of the following symptoms: neurological, dermatological, hematological, hepatological, and cardiovascular. In addition, information on risk factors for cardiac disease, methylene chloride exposures, and work practices and personal protective equipment used during such exposures should be gathered.

Physical Examination. The extent and nature of the physical examination should be determined based on the health status of the employee and analysis of the medical and work history. During the physical examination, the physician or other licensed health care professional shall pay particular attention to the lungs, cardiovascular system (including blood pressure and pulse), liver, nervous system, and skin.

Laboratory Surveillance. The physician or other licensed health care professional shall determine the extent of any required laboratory surveillance based on the employee's observed health status and the medical and work history.

Other Information or Reports. The medical surveillance shall also include any other information or reports the physician or other licensed health care professional determines are necessary to assess the employee's health in relation to methylene chloride exposure.

Emergency Examinations
The employer shall ensure that medical examinations are made available when an employee has been exposed to methylene chloride in emergency situations. Examinations shall include, at a minimum:

- Appropriate emergency treatment and decontamination of the exposed employee

- Comprehensive physical examination with special emphasis on the nervous system, cardiovascular system, lungs, liver, and skin

- Updated medical and work history, as appropriate for the medical condition of the employee

- Laboratory surveillance, as indicated by the employee's health status

Where the physician or other licensed health care professional determines it is necessary, the scope of the medical examination shall be expanded and the appropriate additional medical surveillance, such as referrals for consultation or examination, shall be provided.

Provision of Information
The employer shall provide the following information to a physician or other licensed health care professional who is involved in the diagnosis of methylene chloride–induced health effects:

- A copy of OSHA's Methylene Chloride Standard in 29 CFR 1910.1052

- A description of the affected employee's past, current, and anticipated future duties as they relate to their methylene chloride exposure

- The employee's former or current exposure levels, or, for employees not yet occupationally exposed to methylene chloride, the employee's anticipated exposure levels in normal and emergency situations

- A description of any personal protective equipment used or to be used (e.g., respirators)

- Information from previous employment–related medical surveillance of the affected employee that is not otherwise available to the physician or other licensed health care professional

For each physical examination required by this section, the employer shall ensure that the physician or other licensed health care professional provides the employer and the affected employee with a written opinion regarding the examination results within 15 days of completing and evaluating medical and laboratory findings, but not more than 30 days after the examination. The written medical opinion shall be limited to the following information:

- The physician's or other licensed health care professional's opinion concerning whether the employee has any detected medical condition(s) that would place the employee's health at increased risk of material impairment from exposure to methylene chloride

- Any recommended limitations on the employee's exposure to methylene chloride or on the employee's use of protective clothing or equipment and respirators

- A statement that the employee has been informed by the physician or other licensed health care professional that methylene chloride is a potential occupational carcinogen, that it increases risk of heart disease, and that it can exacerbate underlying heart disease by being metabolized to carbon monoxide

- A statement that the employee has been informed by the physician (or other licensed health care professional) of the results of the medical examination and any medical conditions resulting from methylene chloride exposure that require further explanation or treatment

The employer shall instruct the physician or other licensed health care professional not to reveal to the employer, orally or in the written opinion, any specific records, findings, or diagnoses that have no bearing on occupational exposure to methylene chloride.

4.4 Respiratory Protection

Employees who are required to wear positive- or negative-pressure respirators must obtain written medical clearance from a physician to use this equipment. This medical qualification represents an assessment by a physician that the person in question will not be placed at elevated risk of injury or illness as a consequence of wearing the respirator. In addition, OSHA has issued specific medical surveillance requirements for employees who wear respirators, and has included specific respirator requirements in its substance-specific regulations.

In its Respiratory Protection Standard, OSHA does not identify the specific tests or examinations to be included in the respirator qualifying physical examination. However, the American National Standards Institute (ANSI) publication that addresses physical qualifications for respirator users (ANSI Z88.6-1984) identifies medical conditions that may preclude or limit the extent to which respirators may be worn by an individual, including those conditions presented in Table C2-3.

Employees who use, or may be required to use, respiratory protective devices shall receive a respirator physical examination prior to employment, and annually thereafter. After completing the examination, the physician will submit a written opinion on each employee's respirator qualification status to the EPA laboratory.

4.5 Hearing Protection

At EPA laboratories where hearing protection devices are used to reduce occupational noise levels, an audiometric testing program must be established for all employees whose exposures equal or exceed an 8-hour TWA action level of 85 decibels. Within 6 months of an employee's first exposure at or above the action level, EPA laboratories must establish a valid baseline audiogram against which subsequent audiograms can be compared. At least annually after obtaining the baseline audiogram, the laboratory shall obtain a new audiogram for each employee.

Each employee's annual audiogram must be compared to their baseline audiogram to determine if a standard threshold shift

Table C2-3: Physical Qualifications for Respirator Users

Physical Qualification	Description
Hearing Deficiency	The employee's hearing must be adequate to ensure communication and response to alarms and instructions. In addition, the presence of a perforated tympanic membrane (eardrum) may allow absorption of contamination.
Respiratory Diseases	An employee with insufficient pulmonary function may be disqualified from wearing a respirator. Where a question exists regarding pulmonary function, spirometry should be performed.
Cardiovascular Diseases	Since the use of a respirator may place additional stress on the cardiovascular system, existing cardiovascular disease should be carefully evaluated as a disqualifying condition.
Endocrine Disorders	An employee who is subject to sudden loss of consciousness or response ability could be placed in significant danger if such an event were to occur while in a contaminated environment.
Neurological Disability	Loss of consciousness and reduced response ability caused by a neurological condition may disqualify an employee for the same reasons as endocrine disorders. Epilepsy controlled by medication should not necessarily be a disqualifying condition.
Psychological Conditions	Certain psychological conditions, such as claustrophobia, may disqualify an employee from respirator use.
Medications	Past and current use of some medications may disqualify an employee from respirator use.

(STS) has occurred. Following the detection of an STS that is determined to be work-related or aggravated by occupational noise exposure, the EPA laboratory must ensure that the following steps are taken:

- Employees not using hearing protection shall be fitted with hearing protectors, be trained in their use and care, and be required to use them.

- Employees already using hearing protection shall be refitted and retrained in their use and provided with different hearing protection that offers greater attenuation if necessary.

- If additional testing is necessary, or if the employer suspects that a medical pathology of the ear is caused or aggravated by the wearing of hearing protection, the employee shall be referred for a clinical audiological evaluation or an otological examination, as appropriate.

- If a medical pathology of the ear is suspected that is unrelated to the use of hearing protection, the employee shall be informed of the need for an otological examination.

5.0 Medical Recordkeeping

Proper recordkeeping is essential at EPA laboratories because of the nature of the work and its risks. OSHA has issued requirements that must be adhered to at all laboratories concerning access to employee medical records in 29 CFR 1910.1020 and recordkeeping for injuries and illnesses in 29 CFR 1960, Subpart I, for federal agency employees.

Medical records pertaining to bloodborne pathogens must include, among other items, a copy of the employee's Hepatitis B vaccination status and the results of examinations, tests, and follow-up procedures.

Medical records for each employee shall be preserved and maintained in a confidential file for at least the duration of employment, plus 30 years (unless a specific occupational safety and health standard provides a different time period requirement). In addition, whenever an employee (or designated representative) requests access to a record, the EPA laboratory must ensure that the record is provided in a reasonable place, manner, and time (i.e., within 15 working days).

OSHA also requires that, when an employee first enters into employment (and at least annually thereafter), each employer shall inform them of the existence, location, and availability of:

- Medical records
- The person responsible for maintaining and providing access to these records
- Each employee's right to access these records

Logs of occupational injuries and illnesses shall be maintained by each EPA laboratory. Recordable injuries or illnesses must be recorded on an OSHA Form 200-F (or the equivalent) within six working days after the laboratory has been notified of an illness or injury case. This log shall be established on a calendar-year basis and maintained separate from medical records in an easily retrievable form. Under the standard, BBP exposure incidents must also be documented. However, only exposure incidents that require medical treatment (e.g., AZT prophylaxis, gamma globulin) and/or result in illness need to be recorded. A supplemental record of occupational injuries and illnesses must be completed using the OSHA No. 101 form (or equivalent).

Each facility must complete an annual summary of occupational injuries and illnesses. The OSHA Form 200-F annual summary must be completed no later than one month after the close of each calendar year. A copy of this summary shall be posted in a conspicuous location no later than February 1 and must remain in place until March 1.

OSHA Form 200-F and OSHA Form No. 101 shall be maintained for five years following the end of the year to which they relate.

For more information on recording occupational injuries and illness, refer to Chapter A of this manual.

1.0 Introduction

At EPA laboratories, employees may encounter various types of hazards—chemical, physical, biological, and radiological. Laboratory management must familiarize employees with these hazards and their associated risks, since individuals properly trained in handling hazardous agents are much better equipped to minimize the risk of exposure to themselves, their coworkers, and the environment. It is well known that training plays a critical role in preventing workplace injuries and illnesses. A comprehensive training program teaches employees the proper use of safety equipment and the implementation of related procedures and policies. However, the success of a training program depends on how fully management supports these programs and how employees use the information they learn in the training course(s).

The goal of any training program is to ensure that all individuals at risk are adequately informed about workplace operations, their risks, control measures, and what to do if an accident occurs. The training program should be interactive and offered regularly, not simply on an annual basis.

This chapter describes the training requirements of those standards that apply to EPA laboratories, as well as training that is recommended by industry best practices. Most of the training programs discussed in this chapter are mandated by the U.S. Occupational Safety and Health Administration (OSHA) and the EPA. While many of OSHA's standards are performance-oriented, allowing the employers the flexibility to tailor the particular program to specific worksite conditions, many of the training provisions require that particular categories of information be addressed.

EPA Program Requirements
Each EPA laboratory must:

- Conduct a safety, health, and environmental (SHE) training needs assessment.
- Provide each laboratory employee with the required training, both initially and periodically, as needed or required, based on the results of the needs assessment.
- Document and maintain records of training.

All EPA laboratory employees must meet the SHE training requirements specified in EPA Order 1440 and in regional or facility-specific programs.

Program Administration
To effectively manage the training of laboratory employees, responsibilities should be assigned for:

- Conducting a training needs assessment to determine the requirements for training content and frequency
- Coordinating training by:
  - — Developing training agendas and materials and presenting the training internally
  - — Arranging for training to be presented by external resources

- Tracking training needs (e.g., for refreshers, new hires, or job changes)

- Maintaining training records as specified in applicable federal, state, and local regulations

2.0 Training Guidelines

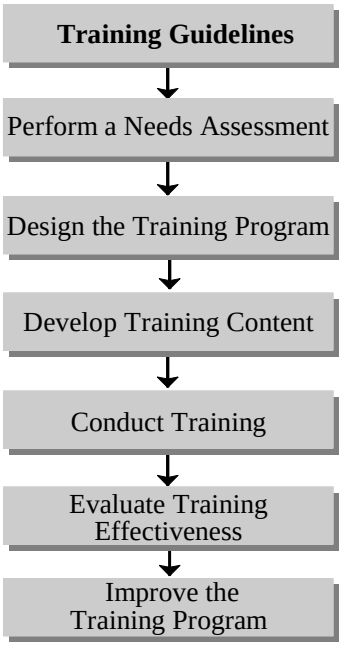
OSHA has developed voluntary training guidelines to assist employers in providing the safety and health information and instruction needed for employees to work with minimal risk to themselves, their fellow employees, and the public. The guidelines provide a model for designing, conducting, evaluating, and revising training programs. The training model can be used to develop training programs for a variety of occupational safety and health hazards identified in the workplace, as well as for environmental issues. It can also help employers meet the training requirements of current or future occupational safety and health standards.

The OSHA training guidelines are designed to help employers to:

- Determine whether a laboratory problem can be solved by training.
- Determine what training, if any, is needed.
- Identify goals and objectives for the training.
- Design learning activities.
- Conduct the training.
- Determine the effectiveness of the training.
- Revise the training program based on feedback from employees, supervisors, and others.

Figure C3-1 presents a summary of training guidelines that are presented in this chapter. Additional training guidelines can be found in the EPA's "Risk Management Through Training" manual.

Figure C3-1: Guidelines for the Development of a Training Program



2.1 Perform a Needs Assessment

The first step in the training model is to determine if a problem can be solved by training. In situations where employees are not performing their jobs properly, it is frequently assumed that training will solve the problem. However, it is possible that other approaches (e.g., hazard abatement, engineering controls) might be more effective in helping employees to perform their tasks correctly. Problems that can be addressed effectively by training include those that arise from lack of knowledge of a work process, unfamiliarity with equipment, or incorrect execution of a task. Training may prove to be less effective in cases where a performance problem is the result of an employee's lack of motivation.

If an employer determines that training is needed, then the first step is to identify specific training needs. One method of determining if additional training may be required is to conduct a job hazard analysis (JHA). A JHA is a method for studying and recording each step of a job, identifying existing or potential hazards, and determining the best way to perform the job in order to reduce or eliminate the risks. Information generated from this activity may reveal a need for additional training. Refer to Chapter B2 of this manual for additional information on JHAs.

As part of the assessment, the audience needing the training should be defined. Training is generally needed when there are:

- New employees
- Transferred employees
- Changes in programs or procedures
- New regulations or requirements
- New equipment or materials
- Needs for improved performance

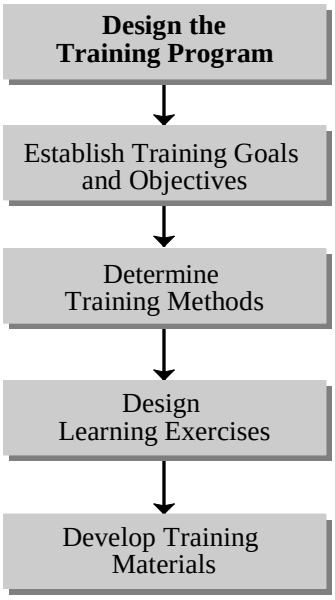
2.2 Design the Training Program

Once the training need has been identified, the next step is to design the program by:

- Establishing goals and objectives
- Determining training methods
- Designing learning exercises
- Developing training materials appropriate for the audience

Each of these steps is described in the following sections and shown in Figure C3-2.

Figure C3-2: Steps in Designing a Training Program



2.2.1 Establish Goals and Objectives

After training needs have been identified, specific goals and objectives for the training should be designated to ensure the usefulness and success of the training. For an objective to be most effective, it should identify, as precisely as possible, what individuals will do to demonstrate that they have learned the desired material, or that the training objective(s) has been reached. Objectives should also describe the important conditions under which the employee will demonstrate his or her competence and define what constitutes acceptable performance.

In its training guidelines, OSHA advises that objectives should designate the preferred practice or skill, and its observable behavior, using action-oriented language. For instance, rather than using the statement: “The employee will understand how

to use a respirator" as an objective, it would be preferable to say: "The employee will be able to describe how a respirator works and when it should be used."

2.2.2 Determine Training Methods

Once the goals and objectives of the training are determined, the next step is to identify the most effective method of training. Selecting methods and materials for the training depends on such factors as the extent of training resources available to the laboratory and the type of skills or knowledge to be learned. The training may be group-oriented and include lectures, role playing exercises, and demonstrations, or it may be designed for the individual with self-paced instruction. Usually a combination of training methods will be used, since some methods will be more effective than others, depending on the key concepts to be presented.

Training Methods
- Open, interactive discussions
- Demonstrations
- Case studies
- Brainstorming sessions
- Hands-on simulations and drills
- Quizzes
- Videos
- Computer-based training

Instructional audio/visual aids may help the trainer to convey important material.

The following are a few guidelines for using visuals as training tools:
- Use visuals to summarize or illustrate main points—not to repeat what is being said.
- Keep text and diagrams simple.
- Use laboratory photographs or other representative graphics where possible.

Audio/Visual Aids
- Diagrams
- Slides
- Films
- Viewgraphs
- Videotapes
- Flipcharts
- Audiotapes
- Blackboard and chalk
- Any combination of these and other instructional aids

2.2.3 Design Learning Exercises

Regardless of the method of instruction, the learning exercises should be developed in such a way that the employees can clearly demonstrate whether they have acquired the desired skills or knowledge. The program should be designed to determine whether the objectives of the learning exercises are being met (e.g., quiz, oral questions and answers, instructor observation of participant demonstration, etc.).

2.2.4 Develop Training Materials

The training materials should be appropriate in content and vocabulary to the educational literacy and language background of participants. This ensures that all employees, regardless of their cultural or educational background, will receive adequate training on how to eliminate or minimize their occupational exposure.

Where commercially available programs are used, ensure that there is an opportunity to provide participants with supplemental facility-specific information.

2.3 Develop Training Content

Initial laboratory training should be provided for all employees. In addition, all employees working in the laboratory are required to attend eight hours of SHE compliance training annually.

Regional and facility laboratory training requirements are designed to comply with the OSHA standard "Occupational Exposures to Hazardous Chemicals in Laboratories" in 29 CFR 1910.1450, as well as EPA Order 1440. Other requirements may pertain to laboratory employees based on their duties and responsibilities (e.g., if they handle hazardous waste).

2.4 Conduct Training

Training should be presented so that its organization and meaning are clear to the employees. To become motivated to pay attention and learn the material that the trainer is presenting, employees must be convinced of the importance and relevance of the material. Trainers are encouraged to follow the training tips provided as follows:

- Prepare for the training session:
  - — Review the material presented.
  - — Ensure that all materials and equipment are ready and in good working order.
  - — Have backups for essential items (e.g., spare projector bulbs).
  - — Check the seating arrangement and layout of the room (e.g., placement of audiovisual tools).
- Explain the goals and objectives of the session.
- Point out the benefits of the training.
- Provide overviews of the material to be learned.
- Relate the training to the employees' interests, skills, and experiences.
- Encourage employee involvement and interaction.
- Reinforce what the employees learned by summarizing the objectives and key points.
- Encourage employee feedback on the effectiveness of the session.

An effective training program allows employees to participate in the training process itself, thereby practicing their skills or knowledge. Employee involvement in training may include:

- Participating in discussions
- Asking questions
- Contributing their knowledge and expertise
- Learning through hands-on experience
- Conducting role-playing exercises

2.5 Evaluate Training Effectiveness

Evaluating the effectiveness of the training program is essential to ensure that the program is meeting its goals. The method for training evaluation should be developed at the same time the training objectives and content are developed. Examples of training evaluation are as follows:

- Questionnaires given to employees
- Informal discussions with employees
- Observations of employees' behavior before and after training

- Changes in the workplace resulting in reduced injury or accident rates
- Observation of training by an external reviewer or auditor

2.6 Improve Training Program

If evaluation of the training reveals that it did not provide employees with the level of knowledge and skill that was expected, then it may be necessary to revise the training program. In this situation, asking questions of both employees and trainers may provide useful information. Among the questions that might be asked are:

- Were parts of the content already known and, therefore, not necessary?
- What material was confusing or distracting?
- Was anything missing from the program?
- What did the employees learn and what did they fail to learn?

An effective evaluation will identify program strengths and weaknesses, establish whether training goals are being met, and provide a basis for future program changes.

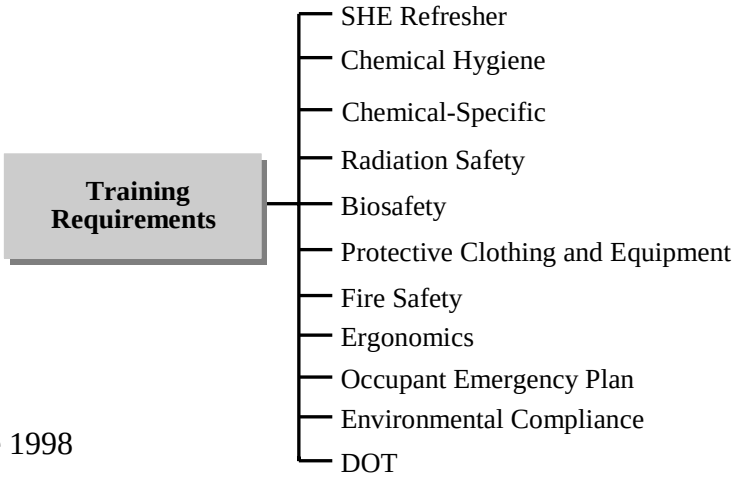
3.0 Overview of Training Requirements

The type and content of training required will vary based on the results of the training needs assessment. The following section provides information on topics for which certain laboratories must provide training. Figure C3-3 outlines the training requirements discussed in this section.

3.1 SHE Refresher

The topics covered in the required annual SHE refresher training for EPA laboratory employees may be determined by each laboratory based on the specific risks, activities, and needs of their employees. Often, laboratories can meet an OSHA requirement for annual refresher training by covering certain compliance elements during the training. For instance, laboratories where employees are designated to fight incipient fires can meet the requirement for annual training by including a session on the use of portable fire extinguishers and associated emergency procedures.

Figure C3-3: Training Requirements for Typical Programs



Common topics for the annual SHE refresher include the following:

- Routes for chemical exposure
- Toxic effects of chemicals
- Means of preventing exposure
- Effective use of ventilation
- Eye, face, and hand protection
- Respiratory protection
- Techniques for reducing health hazards
- Emergency procedures
- Standard operating procedures
- Safe use of laboratory equipment
- Fire extinguishers
- Eyewashes and safety showers
- Chemical spill procedures
- Waste minimization and disposal practices
- Other subjects related to EPA laboratory facilities

3.2 Chemical Hygiene

EPA laboratories must provide employees with information and training so that they will be apprised of both the physical and health hazards associated with hazardous chemicals present in the laboratory. The goal of this training is to ensure that employees are adequately informed about their work in laboratory facilities, the risks, and the appropriate responses in case of an emergency.

Chemical hygiene training is mandated by the OSHA Laboratory Standard. The training provisions of this standard supersede the training requirements of substance-specific standards (e.g., benzene, formaldehyde, methylene chloride), unless otherwise stated by the specific standard. In addition, the training requirements outlined in the laboratory standard supersede, for laboratory employees, the training requirements of the Hazard Communication Standard in 29 CFR 1910.1200.

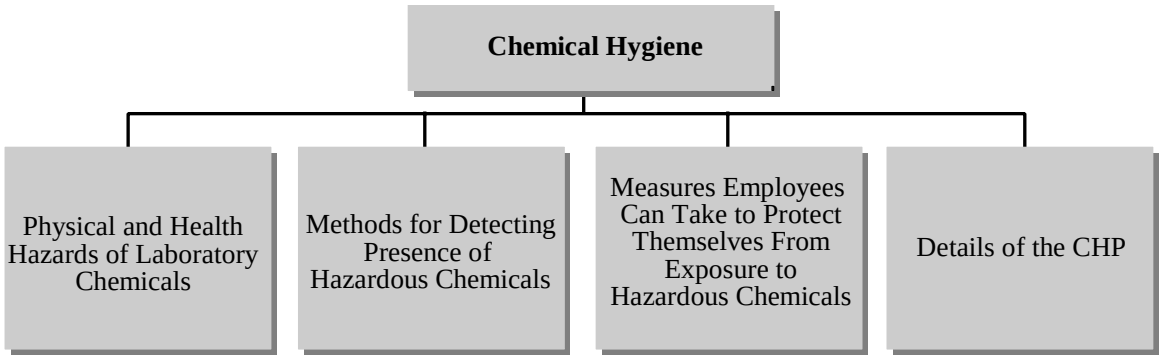
The required training does not necessarily involve training for each specific chemical that the employee will use, but rather the approach may be directed to classes or groups of hazardous chemicals.

Information and training must be provided at the time of the employee's initial assignment and prior to assignments involving new hazardous chemicals or new exposure situations. Typically, new exposure situations include those in which new classes or groups of chemicals are used, or those in which new operations introduce different opportunities for exposure than those performed previously.

The frequency of refresher training may be determined by each laboratory, but the chemical hygiene plan is a topic generally covered during the required eight hours of annual refresher training for EPA laboratory employees. However, more frequent training may be warranted for employees who work in high-risk areas.

After receiving chemical hygiene training, laboratory employees should be familiar with all of the OSHA-required components of training and information under the Laboratory Standard as outlined in Figure C3-4.

Figure C3-4: Chemical Hygiene Training Topics



3.2.1 Physical and Health Hazards of Laboratory Chemicals

This component covers information on the physical and health hazards of chemicals, including those given in the definitions section of the OSHA Laboratory Standard. Generic classes include carcinogens, acutely toxic chemicals, oxidizers, corrosives, etc. This information is essentially the same as that typically provided by training under the Hazard Communication Standard.

3.2.2 Methods of Detecting the Presence of Hazardous Chemicals

This component covers industrial hygiene monitoring methods and the visual appearance and/or odor of particular chemicals or groups of chemicals. Training in this category may also include ways in which employees may be alerted to the presence of hazardous chemicals, such as signs and symptoms of exposure, continual vigilance of workplace conditions, and results of equipment malfunction.

3.2.3 How Employees Can Protect Themselves from Hazardous Chemicals

This component includes details of the customized chemical hygiene plan (CHP) and virtually all of the standard operating procedures (SOP) topics. Training in this category covers specific procedures the employer has implemented to protect employees from exposure to hazardous chemicals, such as appropriate work practices, use of containment and safety equipment, emergency procedures, and personal protective equipment.

In addition, certain required information must be made available and communicated to the employees for chemical hygiene:

- Content of 29 CFR 1910.1450 and its appendices
- CHP, location, and availability of:
  - Exposure limits
  - Permissible exposure limits (PELs) for OSHA-regulated substances

  - — Recommended exposure limits for hazardous chemicals that do not have OSHA PELs

- Signs and symptoms associated with exposures to hazardous chemicals

- Location and availability of reference materials pertaining to chemical hazards; safe handling, storage, and disposal (including, material safety data sheets [MSDSs])

This information may be presented as part of the training program, or made available to employees by other means (e.g., memo, electronic mail). Laboratory employees should be familiar with the "required information" items, and should know how to access this information in their work area or facility.

A sample training outline is provided in Attachment C3-1 of this chapter. Commercially available training materials that address such topics as hazard communication concepts, interpretation of the OSHA Laboratory Standard, and use of laboratory fume hoods, may be an important part of the chemical hygiene training program; however, it is strongly recommended that employers do not rely solely on videotapes, slides, etc., to meet OSHA's training requirements. "Off-the-shelf" materials are not sufficient to address the requirement that employees be trained in the applicable details of their employer's CHP. The most effective training programs are usually interactive and conducted by a person who is familiar with the facility's organization and operations.

Chapter C4 of this manual provides more information on chemical hygiene program requirements. In addition, SHEM Guide 24 addresses chemical hygiene programs and training.

3.3 Chemical-Specific

Where a laboratory is working to implement effective engineering and administrative controls, there may be instances where employee exposures to chemicals regulated by an OSHA substance-specific standard exceed the action level or even the permissible exposure limit. Where this occurs, specific training is required. Chemicals with specific training requirements include those listed in Table C3-1.

Table C3-1: Chemical-Specific Training

Chemical	Regulation
Asbestos	29 CFR 1910.1001
Formaldehyde	29 CFR 1910.1048
Cadmium	29 CFR 1910.1027
Lead	29 CFR 1910.1025
Methylene Chloride	29 CFR 1910.1052
Arsenic (Inorganic)	29 CFR 1910.1018
Acrylonitrile	29 CFR 1910.1045
Methylenedianiline (MDA)	29 CFR 1910.1050
Benzene	29 CFR 1910.1028
1,3-butadiene	29 CFR 1910.1051
Carcinogens (specific chemicals)	29 CFR 1910.1003
1,2-dibromo-3-chloropropane (DBCP)	29 CFR 1910.1044
Vinyl Chloride	29 CFR 1910.1017
Ethylene Oxide	29 CFR 1910.1047

Training recommendations for formaldehyde and methylene chloride, two chemicals commonly used at the EPA that are regulated by a substance-specific standard, are described in the following sections.

3.3.1 Formaldehyde

Appendix A of OSHA's Formaldehyde Standard in 29 CFR 1910.1048 provides information that may be useful in conducting training, such as information on:

- Chemical properties
- Physical and health hazards
- Emergency and first-aid procedures
- Exposure monitoring
- Protective equipment and clothing

Training recommendations for formaldehyde are presented in Table C3-2.

3.3.2 Methylene Chloride

Appendices A and B of OSHA's Methylene Chloride Standard in 29 CFR 1910.1052 contain a substance safety sheet and technical guidelines, as well as information on the toxicology, medical signs and symptoms, and surveillance for methylene chloride exposure. This information is helpful when training employees working with methylene chloride, especially those exposed above the action level. Training recommendations for methylene chloride are presented in Table C3-3.

3.4 Radiation Safety

EPA laboratories must provide adequate radiation safety training of all EPA personnel entering areas of potential radiation exposure to keep exposures as low as

Table C3-2: Training Recommendations for Formaldehyde

Contents of the formaldehyde MSDS
A description of the potential health hazards associated with exposure to formaldehyde and a description of the signs and symptoms of overexposure to formaldehyde
Instructions to immediately report the development of any adverse effects, signs, or symptoms that the employee suspects are attributable to formaldehyde exposure
A description of operations in the laboratory where formaldehyde is present and an explanation of the safe work practices appropriate for limiting exposure
The purpose for, proper use of, and limitations of personal protective clothing and equipment for formaldehyde use
Instructions for the handling of formaldehyde spills and emergencies
An explanation of the importance of engineering and work practice controls for employee protection and any necessary instruction in the use of these controls

Table C3-3: Training Recommendations for Methylene Chloride

Contents of the methylene chloride MSDS
A description of the potential health hazards associated with exposure to methylene chloride (e.g., cancer, cardiac effects, central nervous system effects, liver effects, and skin/eye irritation)
A description of the signs and symptoms of overexposure to methylene chloride
Instructions to immediately report the development of any adverse effects, signs, or symptoms that the employee suspects are attributable to methylene chloride exposure
A description of operations in the laboratory where methylene chloride is present and an explanation of the safe work practices appropriate for limiting exposure to methylene chloride in each job
The purpose for, proper use of, and limitations of personal protective clothing and equipment for methylene chloride
Instructions for the handling of methylene chloride spills and emergencies
An explanation of the importance of engineering and work practice controls for employee protection and any necessary instruction in the use of these controls

reasonably achievable (ALARA). All training and dissemination of information should correspond to an employee's duties, workplace assignment, and responsibilities. The goals and requirements of the EPA's radiation safety training program are provided in the SHEM Guide, Chapter 38.

A radiation safety orientation is required for all new employees at EPA laboratories upon beginning work, regardless of their duties. Additionally, all employees who will work with radioactive materials at the laboratory are required to complete a basic radiation safety training course. Refresher training in basic radiation safety is required at least once every two years for all employees in the radiation monitoring and dosimetry program.

The introductory radiation laboratory work practices course may also be required. This course may be waived by the radiation safety officer (RSO) based on a verifiable record of the employee's past training and experience. Additional topics may be included in the course, or training may be shortened for EPA employees at Regional Laboratories, where on-site radioactive sources are limited to only sealed sources used in analytical instruments (e.g., Ni-63). At a minimum, a biennial refresher course in radiation laboratory work practices is also required.

All radiation training is scheduled and organized by the RSO. Appropriate training videos or interactive computer-based training programs can be useful in course presentations. All personnel radiation training records are maintained by the RSO or SHEMP Manager and the Laboratory Director.

3.4.1 Basic Radiation Safety

The core instructional materials for the basic radiation safety training course can be provided by SHEM Division and Office of Radon and Indoor Air (ORIA), and consist of an instructor lesson plan, student handbook, videotapes, viewgraphs, and a question bank, or similar CD-ROM. Presentation of these materials will be accompanied by discussion and a question-and-answer period. EPA laboratories are encouraged to supplement the core training material to meet locally identified special radiation safety training needs. Course topics for presentation and discussion include, but are not limited to:

- Comparison of ionizing radiation with other hazards
- Types of ionizing radiation
- Radiation measurements, dosimetry, and bioassay
- Types of radiation exposures and doses, with appropriate units
- ALARA principles and philosophy
- Risk, health effects, and the linear non-threshold concept
- Internal and external radiation hazards
- Radiation exposure, administrative limits, action levels, and dose limits
- Radiation exposure during pregnancy*
- The time, distance, and shielding concept
- Applicable radiation exposure regulations
- Identification of the standardized radiation labels that indicate types and quantities of radiation
- Radioactive waste disposal
- Procedures for handling dosimeters and interpreting the results

**This topic is mandatory in each basic course presentation.*

An examination after the basic radiation safety course will document the individual's comprehension of the course material. The examination will be based on the core instructional materials. A minimum score of 80 percent correct answers is required to pass the examination. If an employee does not earn the minimum score, remedial training and retesting shall be provided at the earliest opportunity. The satisfactory completion of basic and refresher radiation safety training courses and examinations must be documented. A record of the specific training course completed, date of completion, and the names of personnel who have fulfilled the training requirements must be maintained by the RSO. Each student should receive a certificate that indicates the successful completion of each course.

3.4.2 Introductory Radiation Laboratory Work Practices

Copies of training requirements, regulations, and other radiation safety-related guidance documents should be included in the material distributed during the course. The topics in Attachment C3-2 should be included in the course to the extent that they have not been covered during the basic radiation safety course. An examination after the course will document the individual's comprehension

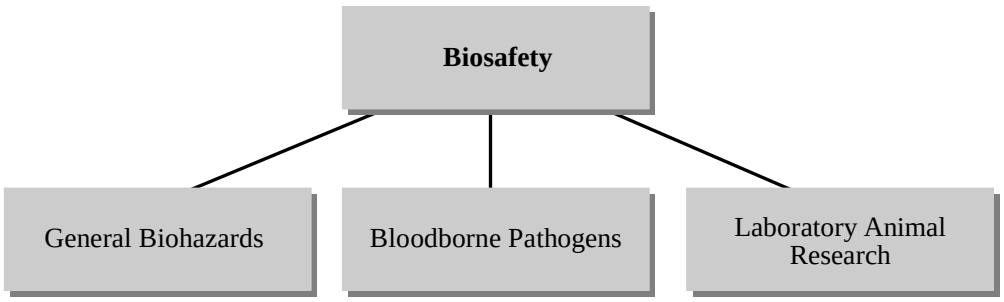
of the course material. The examination will be based on at least 20 questions selected by the instructor. A minimum score is required to pass the examination. If an employee fails to earn the minimum score, the course instructor will administer a review of the material personally, emphasizing weaknesses identified by the examination, and the employee will be retested. The examination will also be used to judge the effectiveness of the course presentation and materials used, and to identify areas that may require improvement.

As part of the overall training program, all employees involved in the use of radioactive materials and radiation-generating equipment should be familiar with 10 CFR 20, applicable National Institute of Standards and Technology handbooks, National Council on Radiation Protection (NCRP) publications, state and local regulations on radiation control, 29 CFR 1910. 1096 and 29 CFR 1910.97. Employees should also be familiar with NRC Regulatory Guides 8.13, and 8.29.

3.5 Biosafety

Biosafety training topics that are discussed in this section and shown in Figure C3-5 include general biohazards, bloodborne pathogens, and laboratory animal research.

Figure C3-5: Biosafety Training Topics



3.5.1 General Biohazard

All EPA laboratory employees must be trained prior to beginning any work with biohazardous agents. Training must be provided on an individual basis at the time of hire or when job responsibilities change. A yearly review must be provided at a general staff meeting.

Technical Staff

Individual training for technical staff members will include:

- The biology of the organisms used in experiments, with emphasis on potential biohazards
- Good aseptic technique
- Proper techniques for decontamination/disinfection
- Emergency procedures
- Safety and health procedures

Before laboratory employees can begin work they must:

- Understand safety and health procedures.

- Demonstrate to the biological safety officer (BSO) a working knowledge of all relevant safety practices, an understanding of the research they will do, and its potential hazards.

- Sign a statement that affirms that the above requirements have been met.

Nontechnical Staff

All nontechnical staff members are to be familiarized with the potential hazards associated with recombinant DNA (rDNA) and biological research in general. As such, these workers will be instructed to recognize areas where biohazardous materials are used (e.g., the meaning of the universal biohazard sign) and the requirements for entry into a laboratory research area.

In addition to the training, custodians and glassware washers must be familiar with the hazards of the areas they must enter to perform their duties. Therefore, they will also be instructed in:

- Waste disposal procedures
- Autoclaving methods
- Emergency procedures for handling spills of biohazardous materials
- Safe work practices while in the laboratory

3.5.2 Bloodborne Pathogens

EPA laboratories must provide all employees who are occupationally exposed to bloodborne pathogens (BBP) and other potentially infectious materials (OPIM) with training on the hazards associated with these agents. Effective training is a critical element in a facility's exposure control plan. Such training will ensure that employees understand the hazards associated with BBP, the modes of transmission, and the use of engineering controls, work practices, and personal protective clothing.

As described in OSHA's Bloodborne Pathogens Standard, in 29 CFR 1910. 1030, training must include an explanation of the elements listed in Attachment C3-3.

BBP training for all employees covered by the standard must be provided at the time of initial assignment to tasks where occupational exposure to BBP may take place.

Additional training must be provided when changes (e.g., modification of tasks or procedures; institution of new tasks or procedures) affect the employee's occupational exposure. At a minimum, employees must receive refresher training annually.

The BBP standard also has specific requirements for documentation of training. These training records must be maintained for at least three years and must contain the following information:

- Dates of the training sessions
- Contents or a summary of the training session
- Names and qualifications of the persons conducting the training sessions
- Names and titles of all persons attending the training sessions

BBP awareness training is recommended for supervisors and other general laboratory employees not covered under the scope of the compliance program. This information can be communicated in any effective format, including a training session, laboratory meetings, bulletins, etc. Recommended topics include:

- Types of (and modes of transmission for) bloodborne pathogens
- Recognition of biohazards (e.g., signs and labels, examples of situations posing a risk of exposure)
- Appropriate actions to take in an emergency involving blood or OPIM
- Procedures to follow in the event of an exposure incident
- Biohazard signs and labels

BBP awareness training should also be documented. Employees working in research laboratories where the Hepatitis B virus and Human Immunodeficiency virus are studied, are subject to the following additional requirements:

- Training and demonstrated proficiency in standard microbiological practices and techniques and specific facility operations

- Experience in handling human pathogens or tissue cultures, or progressive training in work activities if the employee has no prior experience

3.5.3 Laboratory Animal Research

All employees who work with nonhuman primates (NHPs) must participate in training that addresses the following topics:

- Overview of laboratory animal research (LAR) and NHP operations
- Hazards associated with NHP work
- Safety precautions to take when working with NHPs
- Incident response procedures
- Occupational health and medical surveillance program

3.6 Protective Clothing and Equipment

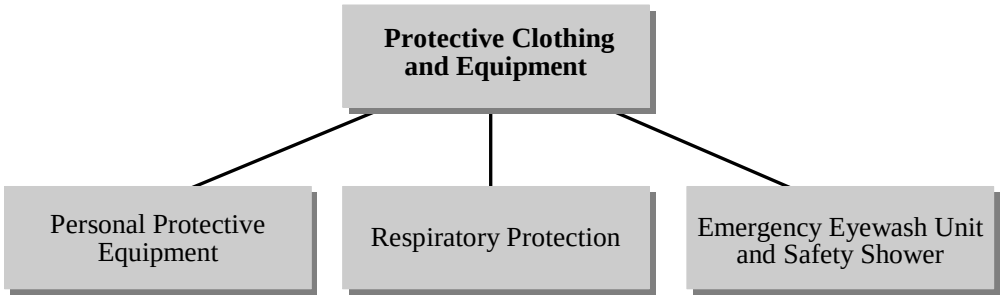
EPA laboratory employees must be trained in the use and maintenance of protective clothing and equipment, as shown in Figure C3-6, including:

- Personal protective equipment (PPE)
- Respiratory protection
- Safety showers and eyewash stations
- Fire extinguishers

3.6.1 Personal Protective Equipment

Training must be provided for each employee required to use PPE. Employees must be able to demonstrate understanding of the topics covered in the training session before being allowed to perform any work requiring PPE. Many facilities administer a quiz to ensure adequate employee understanding; others use frequent workplace inspections as a means to check that employees are properly using and maintaining PPE.

Figure C3-6: Protective Clothing and Equipment Training



PPE training must include:
- When PPE is necessary
- What PPE is necessary
- How to properly put on, remove, adjust, and wear PPE
- Limitations of PPE
- Proper care, maintenance, useful life, and disposal of PPE

Retraining must occur when:
- Changes to the workplace make previous training obsolete.
- Changes to the PPE make training obsolete.
- The employee has not retained the requisite understanding or skill.

Laboratories must certify in writing that the training was carried out and was understood by employees. Training records must include:
- The name of the employee trained
- The date of the training
- The subject of the training (e.g., types of PPE)
- The name of the trainer

3.6.2 Respiratory Protection

The quality and quantity of training provided to respirator users are critical in determining the level of protection afforded in a given situation. At a minimum, the laboratory should offer appropriate training on initial assignment, and whenever the potential for exposure changes. The American National Standards Institute (ANSI) recommends, in its standard on respiratory protection (ANSI Z88.2-1992), that each respirator wearer be retrained annually.

Training requirements for respiratory protection include:
- Functional components of a respirator
- Pre-use inspection
- Air-purifying element selection
- Donning instructions
- Positive/negative-pressure fit checks
- Limitations
- Typical use situations
- Emergency instructions
- Care and maintenance
- Storage locations

OSHA mandates a number of training topics, which are briefly outlined above. In addition to the OSHA requirements, ANSI has recommendations on training topics. Specific contents of training can vary depending the laboratory hazards, but should include:

- The reasons for the need of respiratory protection

- The nature, extent, and effects of respiratory hazards to which the person may be exposed

- An explanation of why engineering controls are not being applied, or are not adequate, and of what effort is being made to reduce or eliminate the need for respirators

- Regulations concerning respirator use

- An opportunity to handle the respirator

- Proper fitting of the respirator, with each wearer receiving fitting instructions that include demonstrations and practice in how the respirator should be worn, how to adjust it, and how to determine if it fits properly

- A long familiarizing period of wearing it in normal air, allowing the wearer to assess comfort; then wearing the respirator in a test atmosphere

- Explanation of why a particular type of respirator has been selected

- Discussion of the respirator's capabilities and limitations

- Instruction, training, and actual use of the respirator

- Explanation of maintenance and storage practices

- Discussion of how to recognize and handle emergencies

Supervisors who oversee the work activity of respirator wearers should have a comprehensive knowledge of respirators and respirator protection practices. Their training should include:

- Basic respiratory protection practices
- Selection and use of respirators to protect workers against every hazard to which they may be exposed
- Nature and extent of the hazards to which the workers may be exposed
- Structure and operation of the entire respiratory protection program
- The legal requirements pertinent to the use of respirators

3.6.3 Emergency Eyewash Unit and Safety Shower

Laboratory employees who may need to use eyewashes or safety showers in emergency situations should be instructed on their proper use and operation, as well as on any inspection or testing procedures required. ANSI recommends, in its Emergency Eyewash and Shower Equipment Standard (ANSI Z358.1-1998), that all employees with a potential exposure to chemical splash be instructed on the topics outlined below:

- Location(s) of eyewashes and showers relative to the user
- Importance of immediate drenching and flushing
- Operation of, and components of, the type of eyewashes and showers in the user's area
- Proper procedures for drenching and flushing, including instructions on how to aid a co-worker
- Testing and maintenance requirements

3.7 Ergonomics

When designing ergonomics training programs, ensure that the following information is included:

- Knowledge of anatomy and musculoskeletal disorders
- Procedures for early reporting of symptoms
- Potential causes of work-related musculoskeletal disorders (WMSDs)
- Personal responsibility for preventing injuries
- Impact of personal habits and work procedures
- Material handling techniques
- Work postures

- Simple workplace modifications and adjustments
- Treatment of WMSDs

3.8 Fire Safety

Fire safety training that is discussed in this section, and presented in Figure C3-7, covers fire extinguishers and fire brigades.

Fire Extinguishers
When portable fire extinguishers are provided for employee use in fighting incipient-stage fires, OSHA requires in 29 CFR 1910.157 that an educational program be provided to familiarize employees with the general principles of fire extinguisher use and the hazards involved with incipient-stage fire fighting. Both initial and annual refresher training is required. Refer to Chapter D of this manual for more information on fire safety and Chapter G of this manual for more information on fire emergency response.

The content of the training is not outlined in the OSHA standard; however, training recommendations for EPA laboratories where portable extinguishers are used for incipient fires include the following topics:
- Basic elements of fire
- Methods for stopping the combustion process
- Classes of fires
- Types of portable fire extinguishers and extinguishing agents
- Review of emergency procedures and notification
- Fire extinguisher use
- Precautions for fighting incipient fires

In addition, "hands-on" training is encouraged for all personnel designated to use portable fire extinguishers.

Fire Brigade
For EPA laboratories that have in-house fire brigades, OSHA requires additional training. Fire brigade team members must be provided with training and education commensurate with the duties and functions they are expected to perform. In addition, fire brigade leaders must be given training that is more comprehensive than the general fire brigade training. For specific training requirements under this standard, refer to OSHA 29 CFR 1910.156(c).

3.9 Occupant Emergency Plan

All EPA laboratories are required to prepare an Occupant Emergency Plan (OEP) outlining procedures for evacuation, hazardous material spills, and other emergencies. All laboratory employees must be trained on the facility-specific emergency procedures outlined in the OEP. Refer to Chapter G for more information on OEPs.

Figure C3-7: Fire Safety Training

Training must include those parts of the OEP that employees need to know to protect themselves in the event of an emergency, as well as any special duties or responsibilities. Therefore, the specific content of the training will be dictated by the OEP itself, as well as the response organization of the laboratory. In general, training should include the following elements:

- Emergency escape procedures and emergency escape route assignments
- Procedures to be followed by employees who remain to operate critical operations before they evacuate
- Procedures to account for all employees who remain to operate critical operations before they evacuate
- Procedures to account for all employees after emergency evacuation has been completed
- Rescue and medical duties for those employees who are to perform them
- Preferred means of reporting fires and other emergencies
- Any special response duties or responsibilities

Training must be conducted initially, whenever the employees' responsibilities or designated actions under the OEP change, and whenever the OEP itself is changed.

3.9.1 Emergency Response

Any laboratory employees designated to respond to an emergency situation must receive training adequate for their duties and responsibilities. Refresher training must be provided at least annually.

Laboratory employees may respond to an incipient spill of a material, which is not considered an emergency, as long as it does not pose a safety or health hazard and can be safely contained and cleaned-up by employees or maintenance in the area.

3.10 Environmental Compliance

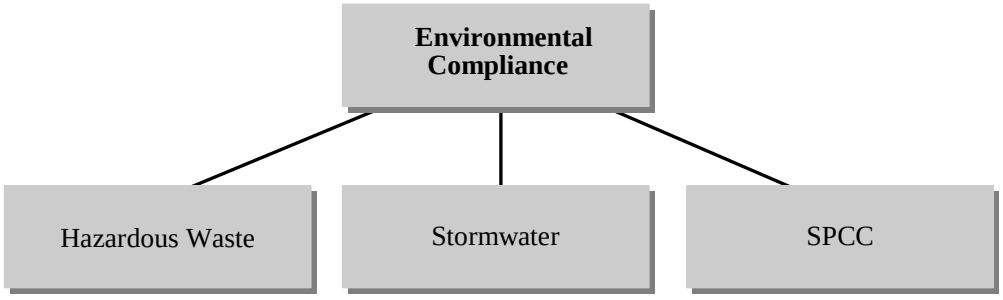
Some laboratory employees may need to have additional environmental compliance training, depending on their duties and responsibilities. Training requirements for hazardous waste and for stormwater best-management practices are discussed in the following sections and shown in Figure C3-8.

3.10.1 Hazardous Waste

Hazardous waste training is required for all generators of hazardous waste, including personnel involved in waste management at any laboratory that meets the criteria for a large-quantity generator. Providing this training to small-quantity generator staff is a good management practice.

The training program should be designed to teach personnel how to perform their hazardous waste management duties in accordance with regulatory requirements. The training may be either classroom instruction or on-the-job training or both. The program must be directed by a person trained in hazardous waste management procedures, and must include instruction that teaches laboratory personnel hazardous waste management procedures (including contingency plan implementation) relevant to the positions in which they are employed.

Figure C3-8: Environmental Compliance Training



At a minimum, the training program must ensure that laboratory personnel can respond effectively to emergencies. The program must teach employees about emergency procedures, emergency equipment, and emergency systems, including, where applicable:

- Procedures for using, inspecting, repairing, and replacing laboratory emergency and monitoring equipment
- Key parameters for automatic waste-feed cutoff systems
- Communications or alarm systems
- Response to fires or explosions using appropriate safety equipment
- Response to groundwater contamination incidents
- Shutdown of operations

Personnel must successfully complete the initial training program within six months of the date of their employment or assignment to a laboratory, or to a new position at a laboratory, whichever is later. Personnel must not work in unsupervised positions until they have completed the training requirements. An annual review of training must be provided to personnel.

In addition to the regulatory requirements, a thorough training program should include training in proper operating procedures for the management of hazardous waste under normal conditions, such as those identified in 40 CFR 262.34 and 265.16:

- Understanding the hazardous properties of laboratory wastes
- Container handling and management
- Manifesting
- Pre-transport procedures
- Recordkeeping
- Contingency planning

The laboratory must maintain the following written descriptions of the training program:

- The job title for each position related to hazardous waste management, and the name of the employee filling each job

- For each job title, a written job description that includes the requisite skill, education (or other qualifications), and duties of personnel assigned to each position

- A written description of the type and amount of both introductory and continuing training that will be given to each person filling a job title

The laboratory must maintain records to document that the training or job experience requirements have been fulfilled. The records on current employees must be kept until closure of the laboratory. Training records on former employees must be kept for at least 3 years from the date the employee last worked at the laboratory.

3.10.2 Stormwater

Where laboratory facilities are permitted to discharge stormwater, the permit also requires implementation of best management practices. Employees with responsibility for preventing stormwater pollution should receive training. Suggested topics include the following:

- Spill control committee
- Material inventory
- Material compatibility
- Reporting and notification procedures
- Visual inspections
- Preventive maintenance
- Housekeeping
- Security

3.10.3 SPCC Plan

Any laboratory required to develop and implement a Spill Prevention, Control, and Countermeasures (SPCC) plan, due to quantities of oil on-site, must also ensure that affected personnel are trained on their duties and responsibilities under that plan. Periodic refresher training sessions should be conducted at intervals frequent enough to ensure adequate understanding of the SPCC plan for that laboratory.

To prevent the discharges of oil, all laboratory employees involved in petroleum management should be trained on the operation and maintenance of oil-using equipment as well as on applicable pollution control laws, rules, and regulations. This information can be communicated during the annual laboratory safety training. Such briefings should highlight and describe known spill events or failures, any malfunctioning components, and any recently-developed precautionary measures.

3.11 DOT

U.S. Department of Transportation (DOT) Training is mandatory for all employees involved in the transport of hazardous materials (i.e., hazmat employees) as specified in HM 126F. The training program must ensure that hazmat employees are familiar with the general provisions of DOT hazardous material regulations found in 49 CFR 172 and 173. The employees must be able to recognize and identify hazardous materials, and have knowledge of:

- Specific employee performance requirements
- Emergency response information
- Self-protection measures
- Accident-prevention methods and procedures

OSHA or EPA training conducted to comply with the hazard communication program (29 CFR 1910.1200 or 40 CFR 311.1) may be used to

satisfy DOT training requirements if the training addresses the above mentioned requirements.

4.0 Training Resources

SHEMD has developed a number of training programs available on CD-ROM. In addition, training assistance may be available through regional offices for some laboratory locations.

Assistance with training programs or the identification of training resources is available from organizations such as:

- Local safety councils (i.e., Association of System Safety Engineers [ASSE] chapters)
- Local industrial hygiene associations (i.e., American Industrial Hygiene Association [AIHA] chapters)
- OSHA full-service area offices
- State agencies that have their own OSHA-approved occupational safety and health programs
- OSHA's Office of Training and Education
- OSHA-funded New Directions grantees

5.0 Training Records

EPA laboratories must maintain training records for all SHE compliance training. Generally, the records should contain the following information:

- Topic of training
- Names of employees attending the session
- Name(s) of instructor(s)
- Date of the training session

Some topics may have additional training documentation requirements that must be followed (e.g., BBP training records as described in section 3.5 of this chapter).

Training records will help to ensure that all employees who need training receive it, that refresher courses are provided at regular intervals, and that documentation is available should it be needed.

The laboratory should maintain training documentation in the facility's central SHE files according to the standard-specific requirements (e.g., three to five years). Some laboratories may have a training database used to maintain and track training by the individual employee as well as the topic. Records should be secure to ensure privacy yet still permit employees to see their files.

Attachment C3-1: Outline for Chemical Hygiene Training Program

Purpose: To provide a sample chemical hygiene training program that meets regulatory requirements.

Instructions: Use this outline as a guide for developing a training program or for updating current training programs.

Training Modules

1 The OSHA Laboratory Standard
2 Physical and Health Hazards
3 Evaluating Chemical Hazards
4 Controlling Chemical Hazards
5 Maintaining Compliance

Module 1: The OSHA Laboratory Standard

1.0 Scope and Application
- Laboratory use/laboratory scale

2.0 Protective Practices
- Administrative controls
- Engineering controls

3.0 Chemical Hygiene Plan
- Procedures/practices for using hazardous chemicals, including safety and health SOPs

4.0 Training and Information
- Identification of physical and health hazards
- Proper work procedures
- Using exposure control measures

5.0 Medical Consultation and Exams
- Provision of medical resources
- Employee's right of confidentiality

Module 2: Physical and Health Hazards

1.0 Physical Properties
- Solubility
- Density, specific gravity
- Boiling and melting points
- Flashpoint
- Explosive, flammable limits

2.0 Physical Hazard Categories
- Combustible, flammable liquids and solids
- Explosives, pyrophorics
- Compressed gases
- Oxidizers, peroxides
- Water reactives

3.0 Health Hazard Categories
- Carcinogens
- Highly toxic materials
- Irritants, corrosives, sensitizers
- Materials with target organ effects

4.0 Chemical Hazards
- Individual
- Multiple

Module 3: Evaluating Chemical Hazards

1.0 Determinants of Exposure
- Concentration
- Duration
- Frequency

2.0 Methods and Observations for Detection
- Signs of the presence of chemicals
- Symptoms of exposure

3.0 Industrial Hygiene Monitoring Methods

4.0 Exposure Limits
- Permissible exposure limit (PEL)
- Short-term exposure limit (STEL)
- Action level

5.0 Material Safety Data Sheets (MSDSs)
- Maintenance
- Requirements
- Elements

6.0 Labeling Requirements

7.0 Hazard Identification and Communication

Module 4: Controlling Chemical Hazards

1.0 General Principles
- Avoid underestimation of risk
- Assume toxicity

2.0 Transporting Hazardous Chemicals
- Containers
- Carts
- Notification

Attachment C3-1: Outline for Chemical Hygiene Training Program

3.0 Storage of Hazardous Chemicals
- Containers
- Identity
- Incompatibility
- Chemical inventory policy

4.0 General Chemical Hygiene Practices
- Preventing chemical ingestion
- Decontamination
- Working alone

5.0 Housekeeping

6.0 Personal Protective Equipment
- Policy
- Types of eye protection
- Respirators
- Glove selection and use

7.0 Laboratory Fume Hoods and Exhausted Enclosures
- Use and function
- Monitoring
- Safe practices

8.0 Safety Equipment
- Types
- Responsibilities
- Inspections

9.0 Proper Handling of Hazardous Chemicals
- Review of hazard classes
- Particularly hazardous chemicals
- Substitution for less-toxic chemicals

10.0 Waste Handling
- Segregation
- Storage
- Removal

11.0 Emergency/Contingency Planning
- Types of emergencies and responses
- Spill response
- Accidents and injuries
- Medical response

Module 5: Maintaining Compliance

1.0 Roles and Responsibilities
- Chemical hygiene officer/committee
- Laboratory supervisors
- Laboratory employees

2.0 Chemical Hygiene Plan Reviews and Updates

3.0 Compliance Inspections

Attachment C3-2: Introductory Radiation Laboratory Work Practices Course

Purpose: To provide a sample training program for radiation laboratory work practices that meets regulatory requirements.

Instructions: Use this outline as a guide for developing a training program or for updating current training programs.

Attachment C3-2: Introductory Radiation Laboratory Work Practices Course

Training Topic	
Basic Principles of Radiation Protection	• Definition of basic terms and concepts – Reduction of external exposure to ionizing radiation – Time, distance, and shielding • ALARA concepts and principles – Reduction of internal contamination – Modes of entry: ingestion, inhalation, absorption – Respiratory protection review – Personal protective clothing – Contamination control
Radiation Monitoring Equipment	• Types of radiation • Principles of detection • Survey equipment: inspection and use
Radiological Surveys	• Direct reading surveys – Dose rate – Contamination (fixed and removed) • Analysis of wipe samples (removable contamination) • Survey forms and results • Contamination action levels
Radiation Dosimetry	• Dose limits – NRC, Presidential Recommendations for Federal Employees – EPA Administrative Limits and Action Levels – Personal dosimetry – External (Thermoluminescent Dosimeters) – Internal (Bioassay) • Reports of personal monitoring results
General Laboratory Practices	• Sample receiving and screening procedures – Receipt – Classification by activity – Sample transfers and spill minimization – Analysis • Safety procedures – Location of safety equipment – Protective equipment use – Safety apparel • Radioactive waste policy – Waste collection/compaction – Determination of discharge limits – Packaging for off-site disposal – Applicable DOT regulations (overview) • Accident procedures – Spills involving radioactive materials – Proper notification – Documentation
Risks Associated with Occupational Radiation Exposure	• Review of radiation protection for pregnant workers • Review of Nuclear Regulatory Commission Guidance Documents – Reg. Guide 8.29, “Instruction Concerning Risks From Occupational Radiation Exposure” – Reg. Guide 8.13, “Instruction Concerning Prenatal Radiation Exposure”

Attachment C3-3: Training Requirements for Bloodborne Pathogens

Purpose: To provide a sample bloodborne pathogens training program that meets regulatory requirements.

Instructions: Use this outline as a guide for developing a training program or for updating current training programs.

Attachment C3-3: Training Requirements for Bloodborne Pathogens

Training Requirements for Bloodborne Pathogens
Contents and availability of the BBP standard
Epidemiology and symptoms of bloodborne diseases
Modes of transmission of BBP
Contents and availability of the facility exposure control plan
Appropriate methods for recognizing tasks and other activities that may involve exposure to blood and OPIM
Use and limitations of methods that will prevent or reduce exposure to such materials, including appropriate engineering controls, work practices, and PPE
Types, proper use, location, removal, handling, decontamination, and disposal of PPE
Hepatitis B vaccine, including information on its efficacy, safety, method of administration, the benefits of being vaccinated, and a declaration that the vaccine and vaccination will be offered free of charge
Appropriate actions to take, and persons to contact, in an emergency involving blood or OPIM
Procedure to follow if an exposure incident occurs, including the method of reporting the incident and the medical follow-up that will be made available
Post-exposure evaluation and follow-up that the employer is required to provide for the employee following an exposure incident
Signs and labels and/or color coding used to communicate biohazard information
Questions and answers with the instructor

1.0 Introduction

Effective management of occupational safety and health at EPA laboratories requires the preparation and implementation of a chemical hygiene plan (CHP) as part of the chemical hygiene program. Developing an accurate and up-to-date CHP offers numerous benefits. In addition to satisfying regulatory requirements, the development of a CHP is a useful exercise in hazard identification, evaluation, and control. A CHP is also a valuable resource and reference for all persons protected by provisions of the CHP. If developed according to the steps outlined in this chapter, a CHP can demonstrate a positive and preventive approach to safety and health, and reflect a laboratory's commitment to employee safety and health. In addition, a CHP can ensure uniformity of work practices within and between laboratories. This chapter provides an overview of the Occupational Safety and Health Administration (OSHA) Laboratory Standard, and describes the steps necessary to prepare a CHP that meets these regulatory requirements.

EPA Program Requirements

In order to realize the benefits described in the introduction to this chapter, each EPA laboratory must:

- Prepare a CHP.
- Comply with the OSHA Laboratory Standard.
- Comply with EPA Order 1440.
- Perform employee exposure determination.
- Provide medical surveillance, when required.
- Provide training.

Program Administration

To effectively implement a laboratory chemical hygiene program, responsibilities should be assigned for the following:

- Developing a written CHP
- Complying with the OSHA Laboratory Standard and EPA Orders
- Determining employee exposure levels
- Providing medical surveillance, when required
- Providing employees with training and information on the hazards in their work areas
- Reviewing and updating the program on an annual basis
- Ensuring that proper controls are in place and are functioning

2.0 Overview of Standards and Regulations

The following sections outline the requirements of the two regulations related to laboratory chemical hygiene: EPA Order 1440 and the OSHA Laboratory Standard, 29 CFR 1910.1450.

2.1 EPA Order 1440

EPA Order 1440, "Occupational Health and Safety Manual," establishes the requirements for the Agency-wide Safety, Health, and Environmental Management Program (SHEMP) and prescribes the basic policy, responsibilities, authority, and general operational instructions for the program.

2.2 OSHA Laboratory Standard

The OSHA Laboratory Standard (29 CFR 1910.1450), titled "Occupational Exposure to Hazardous Chemicals in Laboratories," applies to all employers engaged in the laboratory use of hazardous chemicals, as defined by the standard. The standard is intended to protect laboratory personnel from exposure to hazardous chemicals, and to ensure that any exposures do not reach or exceed acceptable limits.

The federal standard supersedes requirements of all other OSHA health standards found in 29 CFR 1910, subpart Z (e.g., Benzene, Lead, Hazard Communication), except the permissible exposure limits (PELs) and where the action level (or in the absence of an action level, the PEL) is routinely exceeded for an OSHA-regulated substance. Generally, the Laboratory Standard exempts laboratories from complying with detailed requirements of the substance-specific standards that were originally designed to protect workers in industrial, not laboratory, settings. However, in histology, anatomy, and pathology laboratories, the use of formaldehyde is still covered under the OSHA Formaldehyde Standard in 29 CFR 1910.1048. All other uses of formaldehyde in laboratories are covered by the Laboratory Standard.

The Laboratory Standard includes the following requirements:

- Determining which types of work are covered
- Determining employee exposure
- Developing and implementing a written program
- Performing medical surveillance
- Providing training and information

Each of these is described in greater detail later in this chapter.

2.2.1 Scope and Application

The OSHA Laboratory Standard applies to workplaces in which the use of hazardous chemicals occurs on a laboratory scale. Section (b) of 29 CFR 1910.1450 defines *hazardous chemical* and contains definitions of other terms that appear in the standard.

Laboratory use means the handling or use of hazardous chemicals where all of the following conditions are met:

- Chemical manipulations are performed on a laboratory scale.
- Multiple chemical procedures or chemicals are used.
- Procedures are not part of (and do not simulate) a production process.

- Protective laboratory practices and equipment are available and commonly used.

Laboratory scale refers to work with hazardous chemicals in which the containers used for reactions, transfers, and other handling are designed to be easily and safely manipulated by one person.

OSHA has allowed laboratory facilities that fall under the scope of the Laboratory Standard, such as research facilities that conduct large-scale studies, to apply the standard to the entire facility, including non-laboratory work areas (e.g., cage wash, shipping/receiving), as long as the non-laboratory work areas support the research activities. However, the employer may also elect to apply the Hazard Communication Standard and other health standards (instead of the Laboratory Standard) to these non-laboratory work areas. In all cases, other OSHA non-health standards (e.g., respiratory protection, fire protection) also apply.

2.2.2 Relationship Between the OSHA Laboratory and Hazard Communication Standards

The applicability of OSHA's Laboratory and Hazard Communication Standards is summarized in Figure C4-1. OSHA's Hazard Communication Standard in 29 CFR 1910.1200 formalized an employees' right to know about the hazards of the chemicals with which they work. Figure C4-2 provides a summary of the requirements of the standard.

Figure C4-1: Application of Standards to Facilities

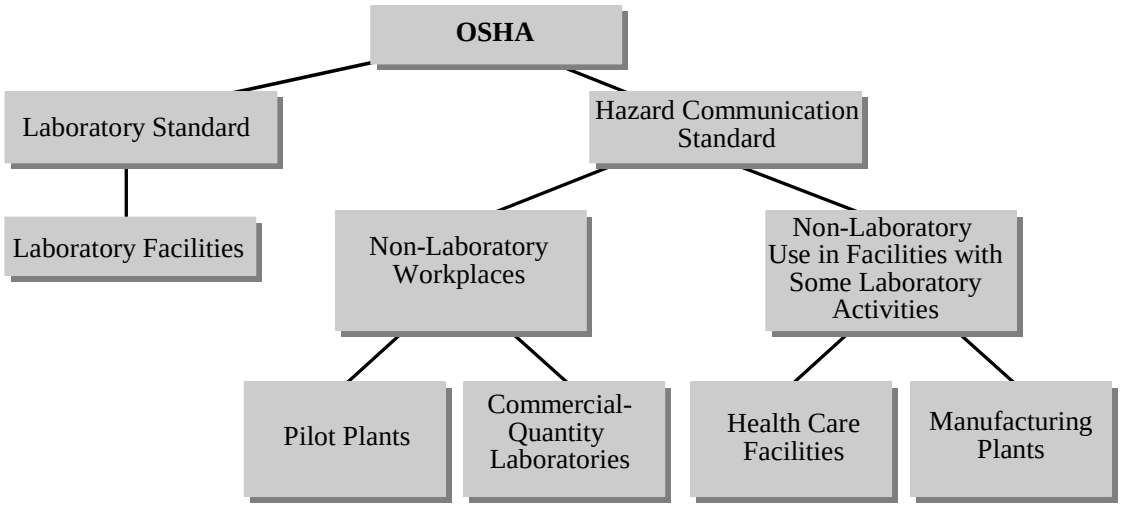
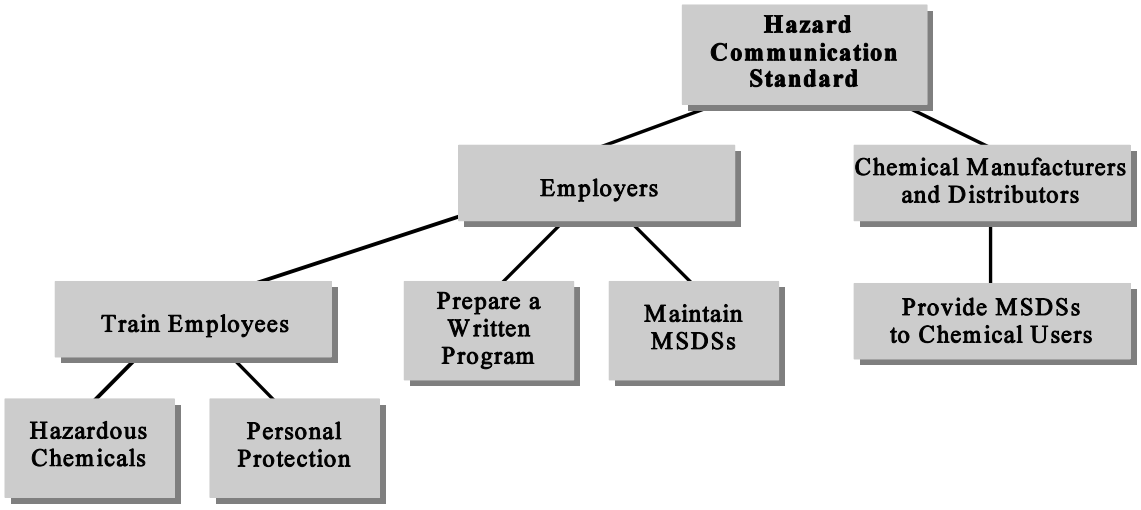


Figure C4-2: Hazard Communication Responsibilities



As laboratories began to implement the Hazard Communication Standard, it became clear that aspects of the regulation, such as the requirement that employers obtain material safety data sheets (MSDSs) for all hazardous chemicals used in the workplace, were more burdensome for laboratories than for general industry. For this reason, OSHA modified requirements for laboratories to encompass the elements presented in Figure C4-3.

OSHA adopted these laboratory-specific portions of the Hazard Communication Standard in the Laboratory Standard. In the Laboratory Standard, OSHA recognized that laboratory employees should have the same degree of protection and right to know about workplace hazards as employees in general industry.

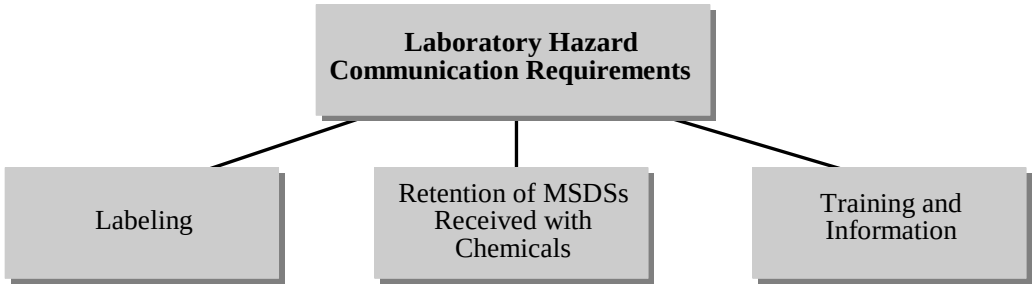
Therefore, when determining the applicability of the Laboratory Standard, employers must ensure that employees receive training and information on hazard communication concepts, whether the training is provided under the Laboratory Standard or the Hazard Communication Standard.

3.0 Chemical Hygiene Program Elements

A chemical hygiene program comprises the following elements:

- Hazard identification and maintaining MSDSs
- Employee exposure determination
- CHP development and implementation
- Exposure controls
- Training and information
- Medical surveillance

Figure C4-3: Modified Hazard Communication Requirements for Laboratories



Each of these program elements is discussed in the following sections and depicted in Figure C4-4.

3.1 Hazard Identification and Maintaining MSDSs

Because the Laboratory Standard reflects key hazard communication provisions, it contains several requirements pertaining to hazard identification and maintaining MSDSs.

3.1.1 Hazard Identification

Hazard identification involves the use of a labeling system for containers of hazardous chemicals. According to the Laboratory Standard, labels should:

- Not be defaced or removed from incoming containers of hazardous chemicals
- Be legible and prominently displayed
- Indicate the identity of the contents at least on secondary containers

Labels are not required for portable containers that chemicals are transferred into from labeled containers as long as it is for immediate use by the employee performing the transfer.

3.1.2 Maintaining MSDSs

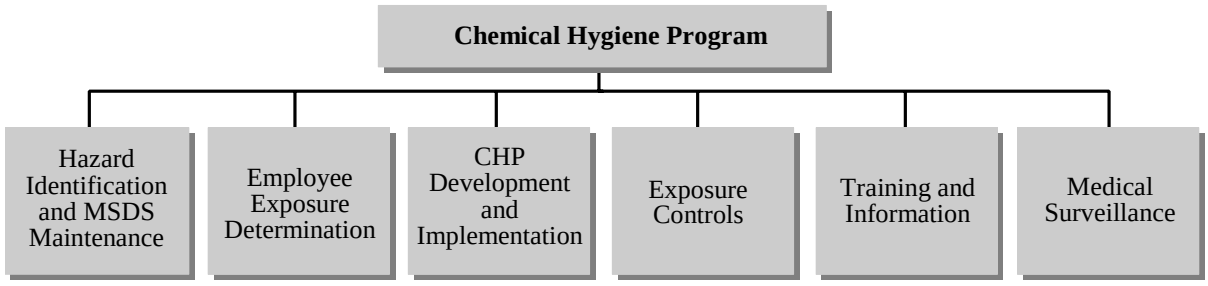
The Laboratory Standard requires that employers retain, maintain, and ensure the employee accessibility of MSDSs that are received with incoming shipments of hazardous chemicals. If a laboratory decides to computerize the MSDS system, hard copies must also be maintained in the event that the computer system fails and to ensure that all employees have access to the information (including those without a computer).

If a chemical is developed in a laboratory, there are additional hazard identification and communication requirements outlined in the Laboratory Standard. If a chemical is produced in a laboratory for another user outside the laboratory, the employer must comply with the Hazard Communication Standard. For most situations, the producer must label containers and provide MSDSs to the user(s).

3.2 Employee Exposure Determination

If there is reason to believe that employee exposure levels for a hazardous chemical routinely exceed the action level or PEL,

Figure C4-4: Elements of a Chemical Hygiene Program



the OSHA Laboratory Standard requires the employer to measure the employee's exposure to the chemical.

For all laboratory workplaces covered under the Laboratory Standard, a chemical hygiene program (including a written CHP) must be developed and implemented, regardless of the outcome of the employee exposure determination.

The following question has to be answered before the chemical hygiene program development process can proceed:

> Are there any operations in the laboratory workplace that may cause employee exposures to OSHA-regulated substances that may routinely meet or exceed the action level or PEL for the substance(s) in question?

To answer this question, follow the steps presented in Table C4-1.

If this evaluation reveals that employee exposures have not routinely exceeded the action level or PEL, then the employee exposure determination is complete. However, if employee exposures have routinely exceeded the action level or PEL, the employer must:

- Perform initial exposure monitoring of employees and operations for which exposures may routinely exceed the action level or PEL. An industrial hygienist or other qualified occupational health specialist has to conduct this part of the employee exposure determination.
- Continue periodic monitoring in accordance with the exposure monitoring provisions of the relevant standard, if the initial monitoring reveals that employee exposure has exceeded the action level or PEL.
- Notify the monitored employee(s) of any results within 15 days after receiving the results. The notification must be written, either to employees individually or posted in an appropriate location accessible to the affected employees.

However, it is prudent to document the exposure determination process to demonstrate that an evaluation was completed.

Table C4-1: Methods to Identify Exposure Potential of an Operation

Step	Description
Establish a chemical inventory.	Use the information available in the MSDSs and reference materials. Record which hazardous chemicals are present in the laboratory. Classify their associated physical and health hazards.
Identify any "particularly hazardous substances."	Make a list of these substances, and ensure that the final CHP contains all provisions necessary for additional employee protection.
Identify any OSHA-regulated substance(s) used routinely in the laboratory.	Compare the chemical inventory to the list of OSHA-regulated chemicals in 29 CFR 1910.1000.
Identify and assess the operation(s) in which the OSHA-regulated chemical(s) is used.	Observe the operation(s), inspect the work environment, and evaluate ventilation systems or other engineering controls to assess whether the operation is likely to produce airborne contaminants at significant levels. A job hazard analysis may also be useful at this stage.

OSHA uses the word "routinely" to describe a situation in which the airborne concentration of a hazardous chemical may be expected to remain at a certain, characteristic level, because of the nature of the workplace environment and the operations performed. Potential overexposures may be indicated by employee complaints or demonstration of signs and symptoms of exposure. Although not required by the OSHA Laboratory Standard, a routine or baseline industrial hygiene survey can also be used to identify potential overexposures.

The EPA's Laboratory Exposure Assessment Program (LEAP) was designed to help laboratories evaluate personnel exposures to chemical, physical, and biological hazards encountered in the laboratory. SHEM Guide 43 provides information on planning, implementing, and assessing the EPA's LEAP.

Refer to Chapter C5 of this manual for information on exposure limits and industrial hygiene monitoring.

3.3 CHP Development and Implementation

The OSHA Laboratory Standard requires that laboratory employers covered by the standard develop and implement a written CHP. The CHP must outline the specific work practices and procedures that are used in the laboratory to control occupational exposures. Implementation of the CHP must:

- Protect employees from the health hazards associated with the hazardous chemicals used in their laboratory.
- Keep exposures below the OSHA PELs.

3.3.1 Elements of a CHP

The CHP must include the following elements:

- Circumstances under which particular laboratory operations require prior management approval
- Provisions for medical consultation and exams
- Designation of personnel responsible for implementing the CHP, including a chemical hygiene officer (CHO) and/or a chemical hygiene committee (CHC)
- Additional protection provisions for work with particularly hazardous substances
- Standard operating procedures (SOPs) relevant to employee safety and health for work with hazardous chemicals
- Criteria that the employer will use to implement control measures to reduce exposures; these control measures can include engineering controls, industrial hygiene practices, and protective equipment
- A requirement that laboratory hoods and other protective equipment function properly and adequately
- Provisions for employee information and training

The CHP must be reviewed and evaluated at least annually and updated as necessary.

A sample table of contents for a CHP is provided in Attachment C4-1 to this chapter. It contains all of the elements required by OSHA, as well as some additional information.

3.3.2 Assembling a CHP

To assemble a CHP, the following steps should be completed:

- Review and revise existing SHEMP documents to reflect current and prudent practice.
- Document any informal policies and practices that support the goals of the chemical hygiene program.
- Develop and write additional SOPs, as needed.
- Integrate the required elements into a comprehensive, laboratory-specific CHP.
- Review the CHP for accuracy and thoroughness.
- Delete details of the draft CHP that do not apply to the workplace(s) for which the CHP is being customized; add other details as necessary.
- Coordinate a critical review of the CHP by staff who are developing and implementing the chemical hygiene program, Include representatives of upper management and/or legal counsel, if appropriate.

3.4 Exposure Controls

The OSHA Laboratory Standard states that for work with particularly hazardous substances, specific consideration must be given to the following:

- Establishing a designated area
- Using containment devices, such as hoods or glove boxes
- Removing contaminated waste
- Decontaminating facilities and equipment

The term *particularly hazardous substances* includes select carcinogens, reproductive toxins, and chemicals with high acute toxicity, as defined in the text of the OSHA Laboratory Standard. At some laboratories, test substances and positive controls are considered *particularly hazardous*. The many controls for handling these chemicals (e.g., barrier system design, balance enclosures) satisfy OSHA requirements for additional protection. EPA laboratories should also ensure that any non-test chemicals that can be considered *particularly hazardous* by OSHA are handled using additional protective measures.

3.5 Training and Information

The OSHA Laboratory Standard requires that employees be provided with information and training to ensure that they are aware of the hazards of the chemicals in their work areas. Training must be provided upon initial assignment to the work area, and prior to assignments involving new exposure situations. The employer is required to determine the frequency of refresher information and training. Refer to Chapter C3 of this manual for more information on designing a chemical hygiene training program.

3.6 Medical Surveillance

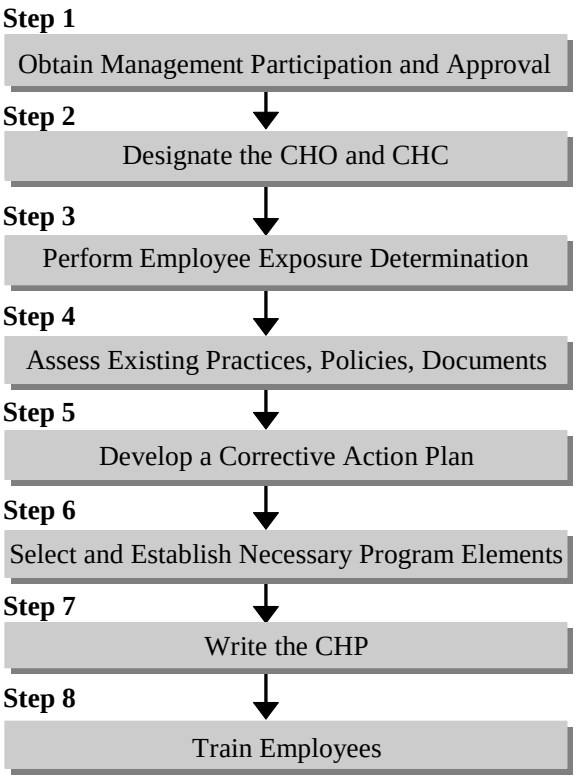
Under the OSHA Laboratory Standard, the employer must provide employees with the opportunity to receive medical attention, including follow-up examinations. For all medical consultations and examinations, the employer must provide specific information concerning potential hazards to the physician. The examining physician should provide a written opinion to the employer that does not reveal specific findings or diagnoses unrelated to occupational exposure.

The laboratory standard also requires that employers establish and maintain an accurate record of any measurements taken to monitor employee exposures and any medical consultation and examinations, including any tests or written opinions. Additional specific information on chemical-specific medical surveillance is included in Chapter C2 of this manual.

4.0 Chemical Hygiene Program Implementation

Laboratories that are developing and implementing a chemical hygiene program for the first time often train employees before the program is fully developed. For new programs, the steps in Figure C4-5 should be completed before employee training is conducted.

Figure C4-5: Chemical Hygiene Program Implementation



Existing chemical hygiene programs should also be evaluated according to these steps. However, additional emphasis would be placed on assessing the strengths and weaknesses of the current program and correcting identified deficiencies.

Each of these steps are discussed in the following sections.

4.1 Step 1: Obtain Management Participation and Approval

For a chemical hygiene program to be successful, laboratory management should participate in the process of developing and approving the program. This approach can help to ensure that the chemical hygiene program is compatible with the philosophy of the laboratory, as well as its activities and other compliance programs. Securing management approval also adds legitimacy to the program. Key staff who will be responsible for implementing the chemical hygiene program should participate in developing the program, so that they will have "ownership" of the project.

4.2 Step 2: Designate the CHO and CHC

The OSHA standard requires that employers designate the personnel responsible for implementing the CHP. Designated personnel include the CHO, whose role is to provide technical guidance in the development and implementation of the CHP. The CHO must be qualified by training or experience to assume this responsibility. A CHC, composed of laboratory management, employees, and other key staff, may also be established to develop and implement the chemical hygiene program.

4.3 Step 3: Perform Employee Exposure Determination

Performing an employee exposure determination is the next step in implementing a chemical hygiene program. Section C4-3.2 of this chapter discusses this in greater detail.

4.4 Step 4: Assess Existing Practices, Policies, and Documents

Next, assess how well existing practices, policies, and documents serve the goals of the program (i.e., to protect employees

from health hazards associated with the chemicals they handle, and to keep exposures below OSHA PELs).

The best way to do this is to conduct a walk-through of the work area(s) to evaluate:

- Work practices
- Use of containment, safety, and personal protective equipment
- Storage and handling of hazardous chemicals
- Use and function of engineering controls

If the work area is complex, an industrial hygienist or other qualified specialist may assist with this activity. The assessment step should include a review of all aspects of the laboratory safety and health program, including the following:

- Administrative control systems
- Engineering controls
- General industrial hygiene and chemical hygiene practices
- Chemical storage, handling, and disposal

Refer to the survey and assessment tools described in Chapter B of this manual for more information.

4.5 Step 5: Develop a Corrective Action Plan

An action plan to correct the deficiencies identified should be developed based on the outcome of assessing existing practices, policies, and documents. The corrective actions may include, for example, any of the following:

- Disposal of obsolete/expired chemicals
- Purchasing flammable-storage cabinets
- Installing eyewashes and safety showers
- Removing clutter from within laboratory hoods
- Obtaining appropriate chemical-resistant gloves
- Updating documentation

If the list of program deficiencies is extensive, it may be necessary to prioritize the corrective actions, so that items directly and significantly affecting the laboratory's compliance status are addressed first.

4.6 Step 6: Select and Establish Necessary Program Elements

To achieve and maintain compliance with the OSHA Laboratory Standard, the management systems presented in Table C4-2 may have to be established as part of the chemical hygiene program.

5.0 Chemical Hygiene Program Maintenance

Once the chemical hygiene program has been developed, it must remain a living document. It should be maintained to ensure that it captures all changes to laboratory operations that may occur. This is accomplished by evaluating its effectiveness and implementation through periodic program evaluations. By reviewing the program as a whole, the laboratory will be able to determine whether established goals and objectives have been met. Necessary updates should be made to the program and revisions forwarded to appropriate persons.

Table C4-2: Management Systems as Part of a Chemical Hygiene Program

Element	Description
Chemical Hygiene Officer	• Develops and implements the CHP • Provides technical guidance
Chemical Hygiene Committee	• Develops and implements the CHP
Monitoring Systems for Administrative and Engineering Controls (e.g., inspection and testing)	• Measure and track performance
Recordkeeping	• Demonstrates performance and completion activities • Includes minutes of the CHC meetings, results of inspection and testing programs, maintenance records, and employee training rosters
Other Provisions for Special Laboratory Activities	• Requires prior management approval • Require review of purchases
Training and Medical Surveillance	• Coordinate programs with appropriate staff

Attachment C4-1: Sample Chemical Hygiene Plan Outline

Purpose: To provide a sample outline of a chemical hygiene plan that contains the information required by OSHA.

Instructions: Use this outline to determine if a chemical hygiene plan meets OSHA requirements. It can also be used as a guide to develop a chemical hygiene plan.

Attachment C4-1: Sample Chemical Hygiene Plan Outline

1.0 Introduction

- 1.1 Policy
- 1.2 Coverage
- 1.3 Availability
- 1.4 Organization, roles, and responsibilities
  - 1.4.1 Chemical Hygiene Committee
  - 1.4.2 Chemical Hygiene Officer
  - 1.4.3 Laboratory Management
  - 1.4.4 Laboratory Employees

2.0 Management Systems Policies

- 2.1 Hazard identification, characterization, and control
  - 2.1.1 Chemical Hygiene Committee review
  - 2.1.2 Employee exposure determination
- 2.2 Employee information and training
- 2.3 Medical consultation and examinations

3.0 Laboratory Practice Policies

- 3.1 General chemical hygiene practices
- 3.2 Housekeeping
- 3.3 Inspections
- 3.4 Glassware handling

4.0 Labeling and Material Safety Data Sheets

- 4.1 Maintaining MSDSs
- 4.2 Signs and labels

5.0 Procurement, Receipt, Distribution, and Storage of Hazardous Chemicals

- 5.1 Chemical procurement, receipt, and distribution
- 5.2 Chemical storage

Attachment C4-1: Sample Chemical Hygiene Plan Outline

6.0 Handling and Transport of Hazardous Chemicals

- 6.1 Handling hazardous chemicals
- 6.2 Handling compressed gases
- 6.3 Transporting hazardous chemicals

Note: Include additional SOPs pertaining to particular chemicals or classes of chemicals as appropriate.

7.0 Facility Design

- 7.1 General laboratory ventilation
- 7.2 Access and security

8.0 Laboratory Containment and Safety Equipment

- 8.1 Monitoring laboratory fume hoods and exhausted enclosures
- 8.2 Inspecting and maintaining safety equipment

9.0 Personal Protective Equipment

- 9.1 Eye protection
- 9.2 Respirators
- 9.3 Glove selection and use
- 9.4 Special personal protective equipment

10.0 Waste Management

- 10.1 Waste handling
- 10.2 Waste storage and monitoring
- 10.3 Waste disposal

Attachment C4-1: Sample Chemical Hygiene Plan Outline

11.0 Emergency/Contingency Planning

- 11.1 Spill response
- 11.2 Accidents, injuries, and illnesses
- 11.3 Emergency medical response
- 11.4 First aid for chemical exposures
- 11.5 Notification procedures

12.0 Recordkeeping

- 12.1 Medical surveillance
- 12.2 Exposure records
- 12.3 Chemical inventory

Figures

Request for Approval of New Chemicals
Chemical Hygiene Inspection Checklist
Chemical Compatibility Chart
Ventilation Inspection Records
Eyewash Inspection Form
Safety Shower Inspection Form
Resistance of Common Glove Materials to Chemicals
Glove Physical Properties Chart
Training Session Attendance Form

Appendices

Chemical Inventory
Chemical Toxicology
Glossary
References
OSHA Laboratory Standard

1.0 Introduction

An effective industrial hygiene program must be an integral part of an EPA laboratory's Safety, Health, and Environmental Management Program (SHEMP). An effective industrial hygiene program is a valuable resource that can help:

- Ensure that employees are not overexposed to hazardous agents.
- Support management goals.
- Verify the effectiveness of control measures.
- Ensure compliance with permissible exposure limits.

In addition, minimization or elimination of employee exposure to hazardous agents can improve morale and productivity, and reduce lost time.

Laboratory operations may create a variety of exposure risks. Often the physical, chemical, and toxicological properties of samples are unknown. Commonly used laboratory reagents may also present exposure risks that require evaluation. Chemicals requiring air monitoring exist in different physical states as described in Table C5-1.

Airborne contaminants are monitored to ensure that employee exposures are being effectively controlled. Chemical exposure monitoring provides data on whether management systems, engineering controls, and work practices are effective in minimizing employee exposure to hazardous chemicals. Exposure monitoring requires identifying and evaluating sources of exposure and subsequently measuring

Table C5-1: Physical States of Chemicals

Gases	Laboratory chemicals may exist as compressed gases under normal testing conditions. Inhalation is the primary route of exposure to gases.
Vapors	Vapors result from the volatilization of a liquid or solid chemical. Inhalation is the primary route of exposure to vapors, while skin absorption of vapors is a secondary exposure route.
Mists	Mists are the aerosolized droplets of a liquid chemical usually created by some mechanical action in a testing procedure. Inhalation and skin absorption are the primary routes of exposure to mists.
Fumes	Fumes are aerosolized solid particulates created by the condensation of a solid that has been heated to form a vapor and then cooled. Inhalation is the primary route of exposure to fumes.
Dusts	Dusts are generally created and dispersed by mechanical action during an analysis of a solid. The size of the dust particle determines the extent of dispersion, and whether it can be inhaled and retained in the respiratory tract. The size of the dust particle also determines where it will be deposited in the respiratory tract. Inhalation and ingestion are the primary routes of exposure to dusts. However, chemically contaminated dust, in some cases, may be absorbed by the skin.

exposure concentrations. Measured concentrations may then be compared to chemical exposure guidelines published by the American Conference of Governmental Industrial Hygienists (ACGIH), the National Institute for Occupational Safety and Health (NIOSH), and the Occupational Safety and Health Administration (OSHA). The industrial hygiene program must be administered in accordance with the EPA's "Laboratory Exposure Assessment Program (LEAP)" as described in SHEM Guide 43.

EPA Program Requirements

The main objective of an industrial hygiene program is to prevent occupational disease and injury through the anticipation, recognition, evaluation, and control of occupational health hazards. To effectively manage an industrial hygiene program, EPA laboratories must consider the following key components:

- A written program and policy statement
- Hazard recognition
- Hazard evaluation and exposure assessment
- Hazard control
- Employee training
- Employee involvement
- Program evaluation
- Recordkeeping
- Compliance with LEAP requirements

Program Administration

Within the industrial hygiene program, responsibilities should be assigned for:

- Performing an employee exposure assessment
- Evaluating sample results
- Implementing control, where necessary
- Communicating results to employees
- Maintaining required documentation of results

2.0 Overview of Standards and Guidelines

This section describes standards and guidelines that apply to industrial hygiene activities in the laboratory.

2.1 OSHA Standards

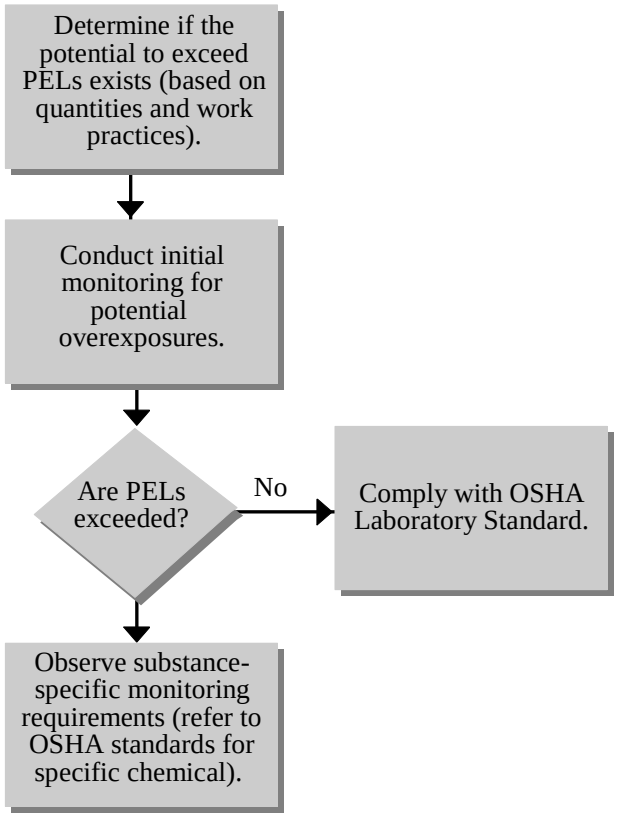
Under the OSHA Laboratory Standard, EPA laboratories are not required to comply with all provisions of the substance-specific standards (e.g., formaldehyde, benzene, etc.). The process used to determine which requirements apply is discussed as follows and is summarized in Figure C5-1. EPA laboratories must:

- Determine if employee exposures to hazardous substances may exceed the permissible exposure limits (PELs) specified by OSHA in 29 CFR 1910, Subpart Z. Many of OSHA's legally enforceable PELs were adopted from ACGIH threshold limit values (TLVs) and NIOSH recommended exposure limits (RELs).

- Conduct initial monitoring to measure employee exposure to any substance regulated by an OSHA standard and that requires monitoring (if there is reason to believe that exposure levels for that substance routinely exceed the action level, or in the absence of an action level, the PEL).

- If initial monitoring reveals that employee exposure exceeds the action level or the PEL, the exposure monitoring provisions of the relevant standard must be observed.

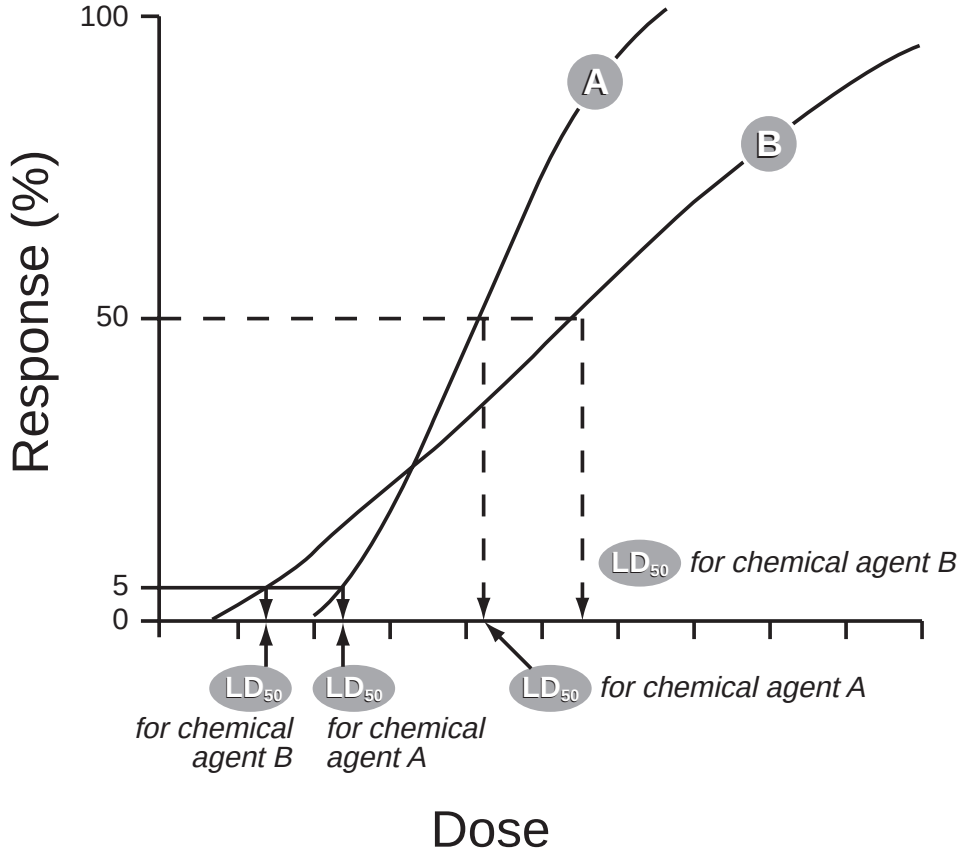
Figure C5-1: Regulatory Decision Process



2.2 ACGIH and NIOSH Guidelines

Exposure guidelines developed by ACGIH and NIOSH are based on the concept that there is a "threshold" dose or concentration for a particular chemical below which no adverse effects will occur. Figure C5-2 demonstrates this in a dose-response curve. These exposure guidelines, expressed as TLVs by ACGIH and RELs by NIOSH, denote airborne concentrations of substances and represent conditions under which, it is believed, that nearly all workers may be repeatedly exposed, day after day, without adverse effects.

Figure C5-2: Hypothetical Dose-Response Curves for Chemical Agents (A and B) Administered to Test Mice



3.0 Exposure Assessment Process

Two approaches may be used to evaluate exposures. The first approach is to compare the *maximum* expected exposure to PELs or TLVs. This is a "worst case" approach to provide conservative estimates of potential exposures. This evaluation uses a maximum number of homogeneous exposure groups (discussed in Section 7.2 of this chapter). To evaluate peak exposures, the 95 percent exposure value is used because only 5 percent of exposures are expected to exceed this value. The second approach compares the *average* exposure in a group to a PEL or TLV.

4.0 Types of Exposure Monitoring

There are four major types of exposure monitoring:

- Personal sampling
- Area air monitoring
- Wipe sampling
- Biological monitoring

Personal sampling, area air monitoring, and wipe sampling are commonly used in toxicology laboratories; biological monitoring is used less frequently unless mandated in a specific OSHA standard. Selection of the correct category depends on assessments that were made when exposures were initially identified.

4.1 Personal Sampling

Personal sampling of an employee's breathing zone is the best method for estimating actual chemical exposure from inhalation. Therefore, if the goal of sampling is to measure an employee's inhalation exposure, then the laboratory should use the breathing zone sampling method. There are four methods of personal monitoring that can be applied to breathing-zone sampling, as described in Table C5-2. These are often used in combination to evaluate an employee's chemical exposure.

Regardless of the monitoring method chosen, it is important to collect enough samples to ensure that exposures can be accurately determined within statistical confidence limits. Typically, a 95 percent confidence limit is considered satisfactory.

A minimum of four personal and four area samples should be collected for each homogeneous exposure group, if possible. For chemicals with a TLV of 50 ppm or less, a minimum of six samples is recommended.

4.2 Area Air Monitoring

Area air monitoring is a technique that can provide a general idea of potential exposures. Sampling devices are placed around the exposure source and areas where employees may work and/or congregate. The results are then used to characterize

Table C5-2: Methods of Personal Monitoring

Personal Monitoring Category	Application
Full-period single	• Samples the concentrations of a chemical over a full shift • Provides a representative assessment of an employee's TWA daily exposure
Full-period consecutive	• Evaluates peak exposures during a full shift with samples taken consecutively • Often used for acutely toxic chemicals when the collection capacity precludes a single, longer sample • Creates a larger sample size, resulting in improved statistical analysis of the exposure data
Partial-period consecutive	• Used when an employee's exposure will remain reasonably constant over a full shift • Estimates an employee's daily exposure if enough sample is collected to meet the detection limit
Grab	• Provides a "snapshot" of the chemical's airborne concentration • Identifies task-related exposures and areas of highest concentration • Determines whether exposure control methods are effective

how source emissions behave. Use caution when characterizing employee exposure with this method. Studies have shown that this technique may significantly underestimate or overestimate personal exposures. This is especially true when environmental conditions (e.g., air currents) fluctuate significantly.

4.3 Wipe Sampling

Wipe sampling is a method used to investigate chemical dispersion from an exposure source. Surface area wipes are used to determine if a particular chemical has been significantly dispersed throughout the work area. This method can also be used to assist in determining whether an employee's protective equipment has been contaminated.

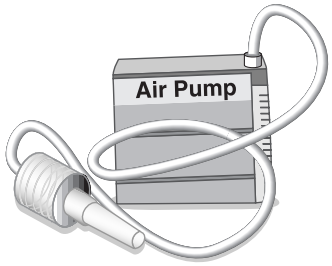
4.4 Biological Monitoring

Laboratories may use biological monitoring to determine whether an employee has received a significantly acute or chronic chemical exposure. For example, cholinesterase levels may be measured to determine exposure to certain organophosphate and carbamate compounds.

Biological monitoring is useful in cases where air sampling is inappropriate (e.g., when the route of exposure is through skin absorption) and in determining whether medical treatment is necessary. It is important that the laboratory obtain an employee's baseline of potential contaminant prior to exposure, so that significant changes resulting from work-related exposures can be identified.

5.0 Equipment and Instrumentation

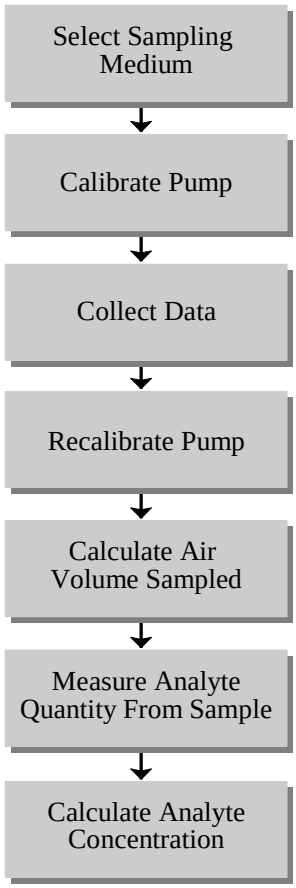
Numerous sampling methods, including those developed by OSHA, are available for monitoring a wide variety of chemical concentrations and/or exposures. Some involve sampling with an air pump, which is used to draw contaminated air through a sampling train (e.g., personal pump, air tube, and sorbent tube or filter cassette) at a constant flow rate.



An investigator may collect chemical contaminants for analysis by filtration, absorption, or using a preselected sampling medium. When in doubt about a specific sampling technique, an AIHA-accredited laboratory (one that has been formally approved by the American Industrial Hygiene Association) should be contacted for guidance.

It is important that the investigator select the correct sampling medium and calibrate the air pump flow rate both before and after monitoring. After collection, the investigator should calculate the volume of air sampled, and once the quantity of analyte collected on the sampling medium has been measured, the concentration of analyte in the air can be calculated. Figure C5-3 outlines the sampling procedure.

Figure C5-3: Sampling Procedure



Passive dosimeters can be used to collect gaseous contaminants in the air by diffusing the analyte through a membrane onto a sorbent. Passive monitoring devices do not require any calibration prior to or after use, and they have the advantage of being easily transportable and simple to use. Numerous passive-dosimetry products that can measure a variety of specific gases are available on the market.

6.0 Selecting a Monitoring Technique

Laboratories selecting a monitoring technique should consider the following:

- Possible routes of exposure and expected airborne concentrations of the chemical
- Physical, chemical, and toxicological properties of the agent to be monitored
- A representative sample size, and whether the need to measure peak exposures (e.g., a short-term exposure limit [STEL] or a ceiling limit [C] exists for the agent)
- The environmental conditions that could affect the sampling methods, such as temperature, humidity, air currents, and other operations in the area, and the physical and time constraints on sampling the operation
- The range of possible exposure levels
- Potential interferences, and the method's detection limit, range, precision, and accuracy

The manufacturer's information for the analyte will be a useful resource to identify factors that may compromise results (e.g., environmental conditions, interferants, etc.).

7.0 Sampling Plan

The plan should be concise, clearly written, and include, at a minimum, the following basic components:

- Background information collected when monitoring priorities were assessed

- Objectives and goals of the exposure monitoring
- Sampling methods to be used, including equipment needs, procedures, and sample containment and preservation
- Justification for selected methods and procedures
- Sample locations and the number and types of samples to be collected at each location
- Sampling frequency

These sampling plan components may be changed, or others added, depending on the specific needs of the laboratory. A plan of action should be developed to ensure that the objectives of exposure monitoring activities are being met.

7.1 Monitoring Priorities

Before beginning exposure monitoring, laboratories should assess monitoring priorities. Ideally, a laboratory should monitor all its operations and personnel; however, this is usually impractical. Therefore, the laboratory must specify monitoring priorities for highly hazardous chemicals or for those employees who may be highly prone to chemical exposure.

A planning committee (e.g., a chemical hygiene committee) should conduct a preliminary walkthrough survey of the laboratory to identify and prioritize operations and chemicals that present the greatest health risk potential. After the operations, chemicals, and affected personnel have been identified, the committee should structure homogeneous exposure groups and a sampling strategy.

7.2 Homogeneous Exposure Groups

Homogeneous exposure groups (HEGs) are selected based on job description or activity and potential for exposure. The industrial hygienist chooses HEG participants on the basis of a walkthrough, noting the various operations, chemicals used, and potential for exposure.

Determinations may also be random. The number of persons monitored should take into account the total number of people in a given area and the number of people per job description in order to ensure uniform representation.

7.3 Sampling Strategy

A sampling strategy should encompass, prioritize, and balance need, resources, implementation, and cost. Sampling programs may be baseline, routine, or compliance-oriented. The majority of sampling is compliance-oriented, evaluating one or two processes, and then never repeated unless a concern arises, such as a process change.

Ideally, for each job task and work process, a sampling strategy should include personal and area samples. Once exposures or potential exposures have been identified, routine monitoring can then be conducted on a periodic basis to detect changes from the baseline or initial survey.

The primary purpose of the sampling program should be considered. This will determine whether personal, area, or both types of samples should be collected. Personal sampling identifies exposures based on a given job task or work process, while area sampling is useful in evaluating the effectiveness of control measures such as ventilation.

Work procedures are also important to consider when developing sampling strategies. A walkthrough survey must be conducted to determine differences in procedures or staffing. All procedures should be monitored in an initial survey unless there are no discernible differences. Then, during routine surveys, the monitoring should be rotated through each shift. Additional information can be found in SHEM Guide 43, "Laboratory Exposure Assessment Programs."

8.0 Potential Difficulties in Sample Collection

A number of difficulties may be encountered in performing chemical exposure assessments. These include, but are not limited to, the following:

- Sampling equipment calibration errors
- Sample contamination
- Varying environmental conditions
- Lack of sample homogeneity
- Absorption of analyte onto sample container walls
- Use of improper sampling medium or method
- Incomplete desorption of analyte from sampling medium
- Channeling of analyte on the collection medium
- Degradation of analyte prior to analysis
- Mechanical defects in sampling equipment
- Partial vapor pressure effects of gases
- Reactivity of the analyte with sampling medium
- Volumetric errors and sampling rate errors
- Temperature and pressure effects during sampling
- Improper packaging and shipping
- Analytical errors
- Calculation errors
- Personnel not professionally competent to conduct the sampling
- Inadequate replicate samples

Listing the variety of precautions that should be taken to avoid these difficulties is beyond the scope of this manual; however, the person conducting the sampling should consider whether these sampling problems may affect the specific chemical monitoring technique being used. Typically, methods published by NIOSH and OSHA give information on common problems (e.g., appropriate ranges, interferences, etc.).

9.0 Evaluation of Sample Results

Once the sampling has been completed, several steps should be taken depending on the outcome of the testing. If the sampling results are negative (i.e., below the action level or PEL), and are representative of employee exposures, the results should be reported to the employees sampled, and documented and filed for future reference.

If the sampling results are positive (i.e., exposure is above the action level or PEL), then both immediate and long-term steps should be implemented. In cases of highly toxic compounds, the operation should be discontinued until additional controls can implemented. In situations involving less-toxic compounds, various types of personal protective and engineering controls should be implemented to provide both immediate and long-term protection to the employees.

Finally, after implementing permanent controls, further sampling should be conducted to verify their effectiveness.

10.0 Communication of Sample Results

As required by the OSHA Laboratory Standard and OSHA's standard concerning access to employee exposure and medical records in 29 CFR 1910.1020, employees must be notified of monitoring results within 15 working days after the laboratory receives the results. The notification must be made in writing, either on an individual basis, or by posting results in a location that is accessible to all employees. In addition, whenever an employee, or designated representative, requests access to a record, access must be provided in a reasonable time, place, and manner.

If access to the record cannot be reasonably provided within 15 working days, OSHA requires that the delay be explained to the requestor within 15 working days. The explanation must include the earliest date the record can be made available.

11.0 Recordkeeping

Laboratories must also establish and maintain an accurate record of any measurements taken to monitor exposures for each employee. OSHA requires that each employee's exposure record be preserved and maintained for at least 30 years. However, background data on workplace monitoring or measuring, such as laboratory reports and worksheets, need to be retained for only one year. This exception applies as long as the sampling results, sampling plan, a description of the analytical and mathematical measurements used, and a summary of other relevant background data are retained for at least 30 years. In addition, OSHA specifies that biological monitoring results designated as exposure records by specific OSHA standards must be preserved and maintained as required by the specific standard.

1.0 Introduction

This chapter provides guidance to EPA laboratories on implementing a radiation safety program (RSP). It provides staff with procedures that will help ensure the safety of personnel where radiation sources are used; radioactive materials are handled, stored, or analyzed; or radiation-generating devices (RGDs) are used.

Practical information for implementing procedures that limit work-related exposures to ionizing radiation, nonionizing radiation, lasers and RGDs is included.

Some EPA facilities and laboratories operate under Nuclear Regulatory Commission (NRC) regulations set forth in 10 CFR Part 30. For this reason, applicable NRC regulations and controls are included in this chapter. However, each NRC license reflects individual laboratory plans, procedures, and agreements as established between the licensee and the regional licensing authority. This information is not intended to supersede, or interfere with, facility protocol that is currently a documented and accepted part of any license. It is intended to assist EPA laboratories in developing procedures for radiation safety and in applying principles that are acceptable to their regional licensing authority, while also meeting Agency standards.

EPA Program Requirements

The Safety, Health, and Environmental Management Division (SHEMD) has established a RSP for all EPA personnel, as described in EPA SHEM Guide 38.

The underlying policy for this program establishes the Agency's position concerning protection of workers from the adverse health risks of occupational exposure to radiation. The policy and program have been devised with the goal of ensuring EPA workers' occupational exposures are as low as reasonably achievable (ALARA), economic and social factors taken into account. The program defines the organizational structure, managerial functions, technical framework, dose limitation system, training requirements, and other elements necessary to achieve this goal.

A memorandum of understanding (MOU) provides for joint management of the program by the Office of Administration (OA) and the Office of Radiation and Indoor Air (ORIA). The MOU affirms the authority of the SHEMD for overall radiation safety and health program administration, and formalizes the relationship between ORIA and SHEMD, wherein ORIA provides technical leadership and support.

Program Administration

To effectively manage the EPA laboratory RSP, responsibilities should be assigned for:

- Developing the necessary written policies, procedures, and instructions to reinforce the ALARA concept
- Performing a formal annual review of the RSP
- Maintaining the sum of the doses received by all exposed individuals at the lowest practical level
- Performing activities to effectively implement the program elements

2.0 Overview of Regulations and Standards

There are a number of federal, state and local standards and regulations that pertain to radiation safety. Those of greatest importance from a compliance standpoint are promulgated by the NRC, NRC Agreement States, the U.S. Occupational Safety and Health Administration (OSHA), and individual EPA laboratory policies and procedures (which may be more restrictive). Each are discussed in the following sections.

2.1 Ionizing Radiation

The following sections present the regulations and standards governing the use of ionizing radiation, as summarized in Figure C6-1.

2.1.1 NRC Regulations

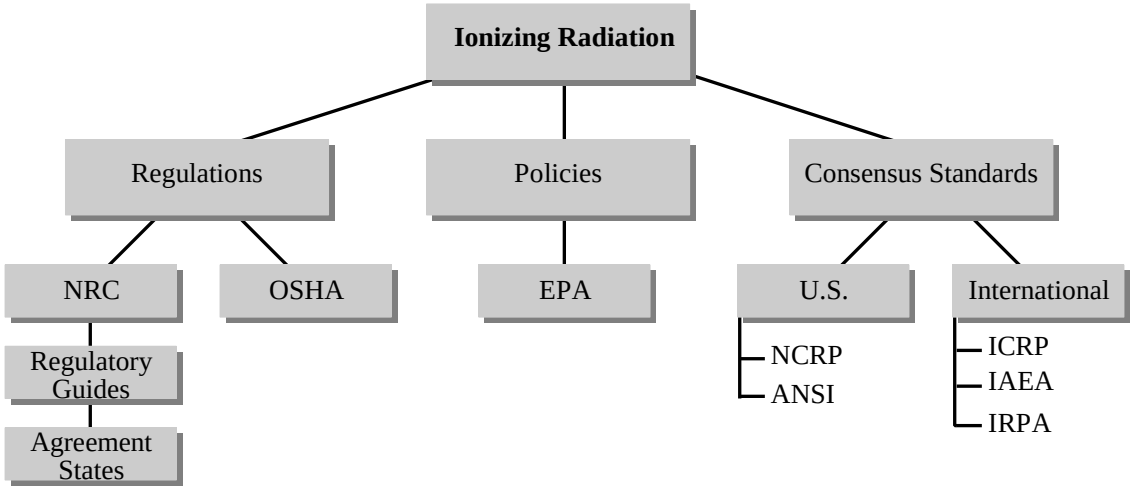
The NRC is an independent federal regulatory agency responsible for licensing and inspecting users of radioactive materials. The NRC's primary responsibility is to ensure that workers and the public are protected from unnecessary or excessive exposure to radiation, and that facilities are constructed to high quality standards and operated in a safe manner. The NRC does this by establishing requirements in 10 CFR Parts 19 and 20 and in licenses issued to radioactive material users.

Many EPA laboratories are licensed by the NRC to use byproduct material and must comply with the NRC's requirements. If a laboratory violates NRC requirements, it can be fined or have its license modified, suspended or revoked.

10 CFR 19

In 10 CFR 19, "Notices, Instructions, and Reports to Workers; Inspections," the NRC presents requirements for posting notices, registering employee complaints or concerns, and providing reports and instruction to employees.

Figure C6-1: Summary of Ionizing Radiation Regulations and Standards



Each licensee is required to post a copy of:

- Both 10 CFR 19 and 10 CFR 20
- The NRC license and operating procedures applicable to licensed activities
- Any notice of violation in areas or laboratories where radioactive materials are used
- Form NRC-3, that describes an employees' rights as a radiation worker as well as the employer's responsibilities

If an employee wishes to register complaints or concerns about radiological working conditions, or other matters regarding compliance with NRC rules and regulations, he or she may contact a representative of the NRC at the following address and telephone number (collect telephone calls are accepted):

U. S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406
(215) 337-5000

Also, to report incidents involving fraud, waste, or abuse by an NRC employee or NRC contractor, contact the Office of the Inspector General at (800) 233-3497.

10 CFR 19 also requires that the EPA, as an employer, instruct its employees in radiation safety in general. Refer to Chapter C3 of this manual for more information on training.

10 CFR 20

10 CFR 20, "Standards for Protection Against Radiation," specifies radiation exposure limits for both workers and the general public, and permissible levels of airborne contamination and effluent. It also specifies standards for establishing personal and contamination monitoring procedures; posting radiation signs; picking up, receiving, and opening packages containing radioactive material; transferring or disposing of radioactive materials; and recordkeeping, report writing, and notifications.

2.1.2 OSHA Regulations

Subpart Z of 29 CFR 1910.1096, "Ionizing Radiation Standards," specifies:

- Limits for exposure of staff in restricted areas
- Precautionary procedures and personal monitoring
- Requirements and exceptions for caution signs, labels, evacuation signals, posting, storage, packaging, shipment, and disposal of radioactive materials

It also specifies requirements for reporting incidents and overexposure, disclosing employee monitoring records, and recordkeeping. It provides that NRC and NRC Agreement State licensees who are in compliance with 10 CFR 20, or equivalent state regulation, are considered to be in compliance with this 29 CFR 1910.1096, Chapter XVII, Subpart Z.

2.1.3 NRC Agreement States

Some states have been given authority by the NRC to regulate users of radioactive materials on behalf of the NRC. These states are called NRC Agreement States. EPA laboratories in NRC Agreement States are licensed by, and follow, regulatory requirements of that state's radiation control board. Table C6-1 presents a list of the states where EPA laboratories are located and whether they must comply with NRC or NRC Agreement State requirements.

2.1.4 EPA Policies

EPA SHEM Guide 38, "Radiation Safety and Health Protection Program," provides information on radiation safety program participation, training, dose limits, monitoring, records, and emergency plans and procedures.

EPA laboratories have established policies that are, in some instances, more restrictive than NRC or NRC Agreement State regulations. Such policies have been designed for the protection of laboratory staff. The provisions for worker safety and health can be augmented by EPA laboratories, but must not be deleted, replaced, or suspended. EPA laboratories use, to the extent practical, procedures and engineering controls based on sound radiation protection principles to set occupational and public dose limits that are ALARA.

2.1.5 Guidelines and Consensus Standards

There are radiation protection organizations that publish guidelines and standards are used to supplement technical knowledge and assist EPA laboratories in complying with regulations. These include the following:

- American National Standards Institute (ANSI)
- National Council on Radiation Protection and Measurement (NCRP)
- International Atomic Energy Agency (IAEA)
- International Council on Radiation Protection (ICRP)
- International Radiation Protection Association (IRPA)

Table C6-1: Agreement State Status

EPA Laboratory Location	NRC	NRC Agreement State
Arkansas		x
California		x
Colorado		x
Florida		x
Georgia		x
Illinois		x
Kansas		x
Maryland		x
Massachusetts		x
Michigan	x	
Minnesota	x	
Mississippi		x
New Jersey	x	
Nevada		x
North Carolina		x
Ohio	x*	
Oklahoma	x*	
Rhode Island		x
Texas		x
Washington D.C.		x

*Agreement state process initiated.

In addition, the NRC publishes regulatory guidelines that provide more prescriptive information on how to comply with the standards. Two widely used regulatory guidelines include:

- NRC Regulatory Guide 8.13, "Instruction Concerning Prenatal Radiation Exposure"
- NRC Regulatory Guide 8.29, "Instruction Concerning Risks from Occupational Radiation Exposure"

2.2 Nonionizing Radiation

The following sections present the regulations and standards governing the use of nonionizing radiation, as summarized in Figure C6-2.

2.2.1 OSHA

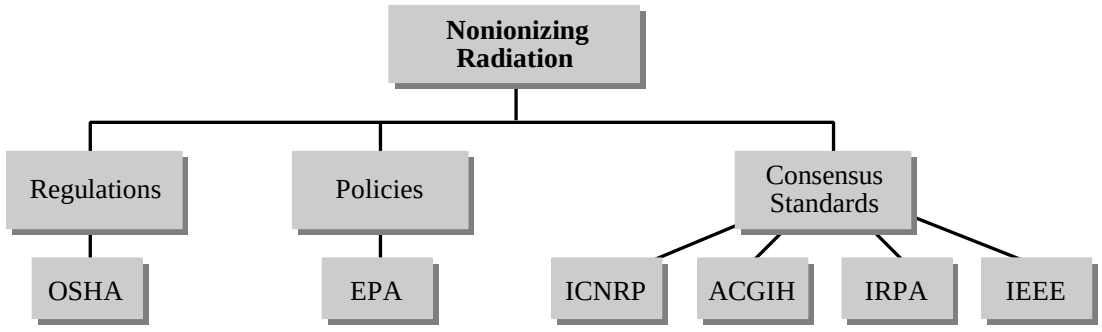
Subpart G of 29 CFR 1910.97, "Nonionizing Radiation Standards," applies to all radiation originating from sources of electromagnetic radiation such as those used for communication, and industrial, and scientific purposes. This section does not apply to the deliberate exposure of patients by, or under the direction of, practitioners of the healing arts. It gives radiation protection guidelines for normal environmental conditions and for incident electromagnetic energy of frequencies from 10 megahertz to 100 gigahertz. These guidelines pertain to whether the radiation is continuous or intermittent, and to both whole-body irradiation and partial-body irradiation.

2.2.2 Guidelines and Consensus Standards

There are a series of guidelines and consensus standards that pertain to nonionizing radiation. The following is a list of some:

- *Guidelines on Limits of Exposure to Static Magnetic Fields,* International Commission on Nonionizing Radiation Protection (ICNRP)
- *Threshold Limit Values for Physical Agents in the Work Environment,* ACGIH
- *Interim Guidelines on Limits of Exposure to 50/60 Hz Electric and Magnetic Fields,* International Nonionizing Radiation Committee of IRPA

Figure C6-2: Summary of Nonionizing Radiation Regulations and Standards



- *American National Standard, Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3 kHz to 300* GHz, Institute of Electrical and Electronic Engineers (IEEE)

2.2.3 EPA Policies

EPA SHEM Guide 38, "Radiation Safety and Health Protection Program," provides information on radiation safety program participation, training, dose limits, monitoring, records, and emergency plans and procedures. Although this provides information on ionizing radiation safety programs, the basic program elements apply to nonionizing radiation safety and should be followed as well.

2.3 Lasers

Laser safety standards promulgated by governmental agencies include the Center for Devices and Radiological Health (CDRH) and model state agencies. Other standards are voluntary, written and promoted by professional or consensus organizations such as ANSI. The following sections present the regulations and standards governing the use of lasers, as summarized in Figure C6-3.

2.3.1 CDRH

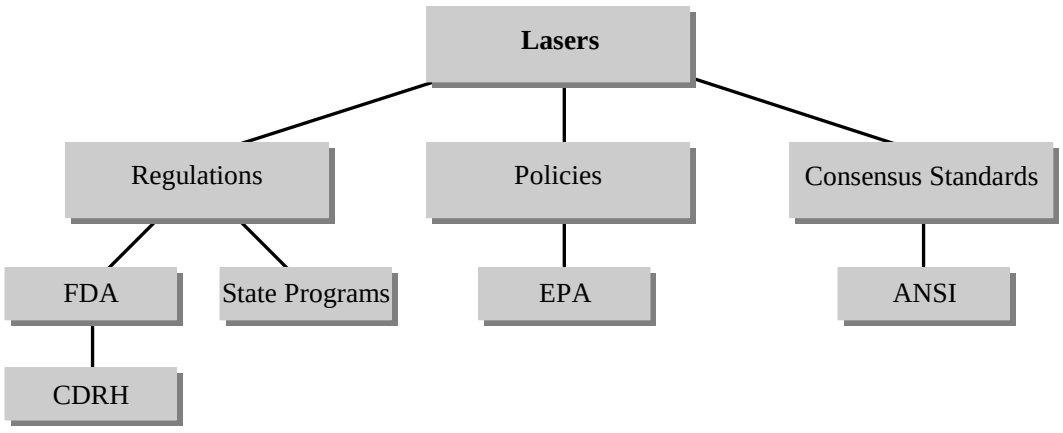
Manufacturers of lasers and laser components are regulated by the federal government's Food and Drug Administration (FDA) through the CDRH. Lasers manufactured after August 2, 1976 are affected by this series of federal standards covering performance, labeling, and informational requirements.

2.3.2 State Laser Regulations

Some states currently have laser regulations. Requirements generally include the registration of lasers and the licensing of operators and institutions.

The complexity of state laser regulations may change in the future pending adoption of the "Suggested State Regulation for

Figure C6-3: Summary of Laser Regulations and Standards



Lasers" promulgated through the Conference of Radiation Control Program Directors. This model state standard has been adopted in part, for example, by Arizona and Florida. Several other states have enacted some form of regulation. Table C6-2 provides a summary of state laser regulations.

Table C6-2: State Laser Regulations

State	Department	Regulation
AK	Env. Conservation	Title 18, Article 7
AR	Div. of Radiation Control and Emergency Mgmt.	Act 460
FL	Dept. of Health and Rehabilitative Services	Non-Ionizing Ch. 10D-80
GA	Dept. of Public Health	Ch. 270-5-27
IL	Dept. of Nuclear Safety	Ch.111 ½
MA	Dept. of Public Health	105 CMR 21
MO	Health and Env. Services	92-003
NY	Dept. of Labor	Code Rule 50
PA	Env. Resources	Ch. 203, Title 25
TX	Dept. of Health	Radiation Control Act Parts 50, 60, 70
WA	Labor and Industry	Ch. 296-62-WAC

2.3.3 ANSI

The ANSI guide, "Safe Use of Lasers," is updated on a regular basis so that it incorporates the most current information. This laser standard is the basis of most other laser safety documents. Its permissible exposure levels and definitions are well accepted in the field. This standard provides guidance for laser use, not manufacture.

2.3.4 EPA Policies

EPA SHEM Guide 38, "Radiation Safety and Health Protection Program," provides information on radiation safety program participation, training, dose limits, monitoring, records, and emergency plans and procedures. Although it does not specifically mention its application to lasers in the laboratory, many of the radiation safety program elements apply to a laser safety program as well.

2.4 Radiation-Generating Devices

The possession and use of RGDs is typically licensed through state agencies. However, there are consensus standards that are used by industry for facility design, RGD installation, and safe operation of a variety of RGDs. For example, ANSI has published the following standards pertaining to RGDs:

- ANSI N43.3: General Radiation Safety–Installations Using Non-Medical X-Ray and Sealed Gamma-Ray Sources, Energies up to 10 MeV

- ANSI N43.2: Radiation Safety for X-Ray Diffraction and Fluorescence Analysis Equipment

3.0 Responsibilities for Radiation Safety

The overall policy, organization, and responsibility for radiation safety and health is described in EPA SHEM Guide 38. This section describes the organization and staff responsibilities for an EPA laboratory where work involving radiation is performed.

The size of the laboratory, type of license and radiological work performed, and the quantities and relative hazard of radionuclides handled or radiation generated, determine the staffing requirements. The Laboratory Director determines if the duties of the radiation safety officer (RSO) require a part-time position, a full-time position, or a full-time position with one or more assistants.

The following sections explain the radiation safety responsibilities of Laboratory Directors, Safety, Health, Environmental Management Program (SHEMP) Managers, the radiation safety committee, the RSO, and individuals receiving dosimetry. Figure C6-4 provides an organizational chart for radiation safety responsibilities.

3.1 Laboratory Director

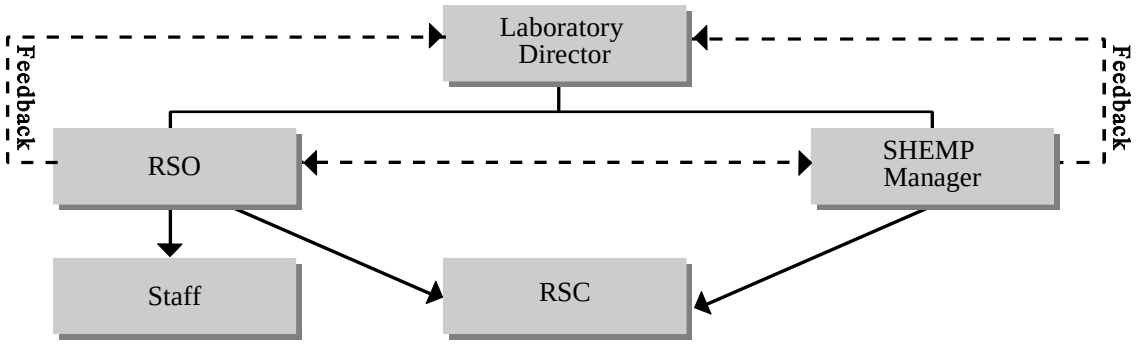
The Laboratory Director has ultimate responsibility for the safety and health of laboratory personnel. The director delegates this responsibility to two staff positions: the SHEMP Manager and the RSO. These staff positions report directly to the Laboratory Director on safety- and health-related matters.

3.2 SHEMP Manager

Depending on local laboratory organization and activities, the SHEMP Manager may assist the RSO by performing the following duties:

- Recommend and review worker enrollment in the monitoring and dosimetry program
- Administer all recordkeeping requirements prescribed by the RSP and provide data accessibility to the RSO
- Serve as the point of contact for the dosimetry service provider(s)
- Disseminate and collect personal dosimeters
- Maintain employee exposure records to include internal and external dosimetry measurements, and make data available to workers as required by the RSP in 10 CFR 19
- Perform quarterly reviews of employee exposure records (e.g., dosimetry measurements), review excursions above established action levels, and investigate other exposure occurrences, in consultation with the RSO
- Ensure that the appropriate protective clothing and equipment are available for employees
- Ensure that all laboratory activities are performed according to established ALARA principles

Figure C6-4: Radiation Safety Organization



- Implement quality assurance (QA) activities

3.3 Radiation Safety Committee

For EPA laboratories that have a radiation safety committee (RSC), the RSC assists the RSO in ensuring radiation safety at the laboratory. This committee, which may be a sub-committee of the laboratory safety committee, is composed of the RSO and representatives from each branch, section, and/or unit in which work involving radiation is performed. The RSO is the committee chairman. The RSC convenes as directed by the RSO and considers all new processes and projects before work begins. Their responsibilities include the following:

- Meet quarterly without fail
- Conduct a review of proposed users and uses of radioisotopes
- Delegate authority to the RSO or designee for implementing and enforcing the ALARA concept
- Encourage all users of radiation to review current procedures to implement the ALARA concept
- Conduct a quarterly review of occupational radiation exposure to assess trends in the ALARA program quality
- Evaluate the laboratory's overall efforts for maintaining doses ALARA on an annual basis

3.4 Radiation Safety Officer

An RSO must be sufficiently qualified in radiation safety specific to the types of materials and equipment being used at the laboratory. An EPA employee should satisfy the following education, training, and experience requirements to be designated an RSO:

- ***Education:*** An academic degree (B.S. or BA) in physical or biological science or engineering is required.

- ***Training:*** Advanced radiation safety training is mandatory for RSOs. At a minimum, successful completion of a 40-hour radiation protection (i.e., health physics) course is required. A refresher course every two years is

also required in order for the RSO to remain current with regulations and technology.

- ***Experience:*** Approximately three years of health protection experience with radiation or radioactive materials is required. Additional education specific to health physics can be applied to satisfy, in part, the experience requirement.

The RSO may be designated as the laser safety officer or nonionizing radiation safety officer if the laboratory uses lasers or nonionizing radiation. In the event that there is no SHEMP Manager assigned responsibility for the laboratory, the RSO is also obligated to fulfill the responsibilities listed for the SHEMP Manager. The alternate RSO acts for the RSO in his/her absence.

3.4.1 Responsibility for Ionizing Radiation Use

The RSO's responsibilities for ionizing radiation use in the laboratory include the following:

- Serve as the chairman of the RSC.
- Recommend and approve worker enrollment in the monitoring and dosimetry program, in consultation with the SHEMP Manager.
- Schedule and provide radiation safety training, and copies of all radiation safety–related material, to all employees that use, handle, or analyze radioactive materials.
- Review excursions above established action levels and other exposure occurrences in consultation with the SHEMP Manager.
- Provide a means to safely store radioactive materials, instruments, personal dosimeters, and related equipment.
- Ensure that all portable survey instruments assigned to the RSO are maintained in effective operating condition and calibration at all times.
- Establish, implement, direct, and supervise radiological monitoring activities at the laboratory.
- Determine the required levels of protective apparel and equipment.
- Process all license applications, amendment requests, and program updates for the NRC or NRC Agreement State.
- Monitor radiological practices at the laboratory to ensure regulatory compliance.
- Process procurement requests for radioactive materials.
- Receive all shipments of radioactive material and deliver, or supervise delivery, to the individuals named on the purchase request.
- Ensure that proper safeguards are in place for the installation of radiation-generating equipment.

- Perform periodic laboratory surveys that include recording contamination levels, smear locations and counts, and any significant exposure rates that may exist in laboratories using radioactive materials.

- Perform quarterly reviews of laboratory survey records, promptly evaluate any anomalies, and insert explanatory remarks into the records.

- Provide exposure calculations for specifically monitored areas.

- In consultation with the Laboratory Director, terminate hazardous or potentially hazardous radiological operations.

- Conduct a continuous program of radiation hazard recognition, evaluation, and minimization.

- Supervise all laboratory radioactive waste disposal operations.

- Ensure that all laboratory activities are performed according to established ALARA principles.

- Work with the SHEMP Manager in implementing QA activities.

3.4.2 Responsibility for Nonionizing Radiation Use

The RSO's responsibilities for nonionizing radiation use may involve assistance by other individuals who are experienced in the use of specialized types of nonionizing radiation such as microwaves, ultrasound, and ultraviolet radiation. The responsibilities of an RSO for nonionizing radiation safety can include the following:

- Maintain personnel and area monitoring records for nonionizing radiation.

- Instruct personnel in the proper use of monitoring devices and nonionizing radiation protection.

- Perform or supervise nonionizing radiation surveys.

- Inspect facilities and equipment where nonionizing radiation-producing equipment is used.

- Suspend or terminate the operation of a nonionizing radiation system if the hazard control procedures are not adequately protecting staff.

- Provide approved personal protective equipment, when necessary.

- Maintain information on the regulations and guidelines pertaining to nonionizing radiation safety and exposure.

3.4.3 Responsibility for Laser Use

The RSO's responsibilities for laser safety include the following:

- Provide information to staff on laser hazard evaluation and control.

- Ensure adequate safety practices are being used.

- Suspend or terminate the operation of a laser product or installation if the hazard control procedures are not adequately protecting staff.
- Maintain information on the regulations and guidelines pertaining to laser safety.
- Approve all personal protective equipment for use with lasers.
- Survey all areas were laser equipment is being used to ensure compliance with regulations.
- Review plans for new installations or modifications to laser equipment to identify hazards.
- Investigate all incidents resulting from laser operations.
- Ensure that adequate warning systems are installed and operating.

3.4.4 Responsibility for RGD

The RSO's responsibilities for RGD safety include the following:

- Establish and implement the RSP for the laboratory.
- Ensure that RGD operating procedures are current and available at each RGD installation for both normal and off-normal operations.
- Ensure that pre-operational inspections are performed.
- Ensure that pre-operational assessments are performed by qualified experts and addressing comments received from the expert.
- Ensure that safety devices and interlocks are located where required and are functioning as designed.
- Coordinate radiation surveys performed by the radiation safety staff.
- Maintain a current inventory of all RGDs.
- Approve inspection and radiation survey results and advising management of the need for corrective actions.
- Terminate unsafe RGD operations.
- Resume operations in conjunction with correction of unsafe conditions.
- Determine the appropriateness of by-passing any safety device.
- Approve any deviation from established procedures.
- Instruct individuals in safe work practices and the nature of injury from overexposure incidents.
- Investigate any incident of abnormal exposure or suspected overexposure of an individual, determine the cause, and implement corrective action.

3.5 EPA Laboratory Staff

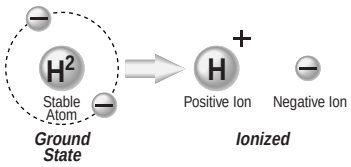
EPA laboratory staff participating in the dosimetry program are responsible to:

- Comply with the requirements set forth in EPA 1440, SHEM Guide 38, and follow standard operating procedures (SOPs), standard methods, and other regulated guidance in the performance of their work.
- Adhere to ALARA principles in all radiation-related work activities.
- Complete all required training on a timely basis.
- Practice proper handling and use, timely exchange of dosimeters issued, and maintaining a dosimeter use log when required.
- Participate in reviews of action level excursions and other exposure occurrences.
- Familiarize themselves with the emergency response plans and procedures at work sites they visit.
- Report prior and concurrent occupational exposure to ionizing radiation from activities for other employees.

In addition to the above responsibilities, females are encouraged to declare pregnancy as soon as known so that fetal protection limits may be instituted.

4.0 Types of Radiation Sources

Radiation is divided into two general categories: ionizing and nonionizing. The normal state of an atom, in which it is stable, is the ground state. Ionization is a process by which electrons may be removed from, or added to, a stable atom.



The removal of one or more electrons from an atom results in an ion pair consisting of the free electron(s) and the positively charged residue. If energy supplied to an atom is sufficient to cause an electron to be raised from one orbital shell to another, the atom is said to be in an excited state. If enough energy is added to remove electrons, the atom will be ionized.

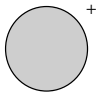
4.1 Ionizing Radiation

Ionizing radiation is any radiation capable of displacing electrons from atoms, thereby producing ions. There are four types of ionizing radiations: alpha particles, beta particles, gamma rays, and x-rays. Their characteristics are summarized in Table C6-3 and discussed in the following sections.

4.1.1 Alpha Particles

An alpha particle is a helium nucleus emitted with a discrete energy and a characteristic half-life from each alpha emitter. Alpha particles are ejected from the nucleus of naturally occurring radioactive atoms and travel along straight paths.

Table C6-3: Types of Ionizing Radiation

Emission	Mass	Charge	Characteristics
Alpha Particle 	4 amu	+2	Helium nucleus Discrete energy Travels along straight paths Produces a large number of ion pairs over a short distance Internal hazard Easily shielded
Beta Particle 	1/2000 amu	-1	Electron Continuous energy spectrum up to a maximum value Interactions occur at less frequent intervals along their path than alpha particles Range is greater in materials than alpha particles May be an external hazard (i.e., skin and corneas) if the energy is high enough
Gamma Ray 	None	None	Electromagnetic energy emitted from the nucleus Interactions produce few primary ions which, in turn, produce few secondary ions Range is long in air and tissue External hazard Extensive absorbing matter or shielding is required
X-Ray 	None	None	Similar to gamma rays except emitted from the outer shell of an atom

The energy of an alpha particle is lost mainly by ionization and excitation of the atoms of the traversed substance. Because of their positive charge and large mass, alpha particles quickly form a large number of ion pairs in a short distance before they lose all of their energy.

Therefore, alpha particles have short ranges in substances and are not an external hazard because they will not penetrate the outer dead layer of skin. They are however a hazard if taken internally where they are effective in causing damage to live cells. Once all their kinetic energy is gone, they pick up two free electrons and become a stable helium atom.

4.1.2 Beta Particles

A beta particle is a high-speed electron emitted from the nucleus of an unstable atom. Unlike alpha particles, betas are not emitted with discrete energies but show a continuous energy spectrum. The atom emits beta particles of all energies up to some maximum value. This maximum and average value for a given beta spectrum may be found in nuclide tables and is characteristic of that radionuclide.

Beta particles lose energy through ionizations and excitations as do alpha particles. In a given substance, a beta particle will undergo a large number of collisions until it eventually loses all of its energy.

The processes leading to ionization in the substance are the same for the beta particle as those for the alpha particle. But because of its smaller mass and lower charge, the interactions take place at less frequent intervals along their path. Therefore, beta particles have greater ranges in materials than alpha particles. As such, depending upon their energy, they may penetrate the external dead layer of skin and deposit their energy in live skin cells.

Since most beta particles are easily absorbed by a small amount of metal or plastic, the hazard will usually exist only very near the source. Beta particles are not as significant an internal hazard as alpha particles. Their greater tissue range means that damage due to ionizations will not be localized as it is for alpha particles. Figure C6-5 shows a comparison of the ranges of commonly used beta emitters.

4.1.3 Gamma Rays

Gamma radiation is pure electromagnetic energy, that is wave-like rather than particulate. When gamma rays interact with matter, only a small number of primary ions are formed. These ions in turn produce most of the ionization (secondary) that occurs in a substance. As such, gamma rays are called indirectly ionizing radiation, whereas alpha and beta particles are called directly ionizing radiations. Gamma rays have a long range in air and in tissue. As such, gamma rays are significant as external hazards. Energy loss is not continuous along their path, it occurs only at interaction sites, therefore they are not as significant an internal hazard as alpha and beta particles. To reduce the hazard, extensive absorbing matter or shielding such as lead or concrete is required.

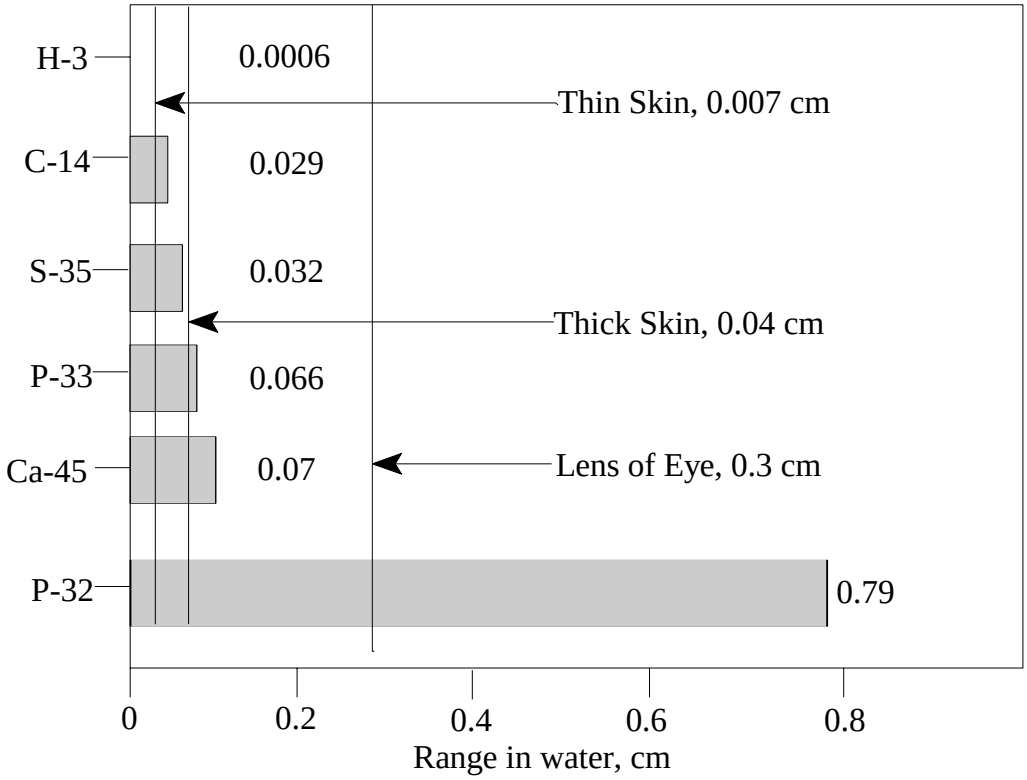
4.1.4 X-rays

X-rays are electromagnetic energy that originate from the outer energy shells of an atom. They are produced when accelerated electrons interact with a target, usually a metal absorber, or with a crystalline structure. This method of x-ray production is known as bremsstrahlung. Many different types of machines produce x-rays, either intentionally or inadvertently. X-rays can also be produced by the attenuation of beta particles emitted from radionuclides.

4.2 Nonionizing Radiation

Nonionizing radiation simply imparts its energy to atoms or molecules in its path by knocking electrons from one orbital shell to another of higher energy. These atoms

Figure C6-5: Comparison of Beta Ranges



and molecules that are in an excited state lose energy through emission of light and return to the ground state. Nonionizing radiation refers to electromagnetic radiations with energies less than 10 electron volts (eV) that include those with wavelengths in the following regions:

- Near ultraviolet (UV)
- Visible (VIS)
- Infrared (IR)
- Radiofrequency (RF)
- Microwave (MW)

Figure C6-6 shows where these types of nonionizing radiation fall in the electromagnetic energy spectrum. As can be seen, these regions include energy in the "optical" region. This region includes radio and television broadcast, power transmission, low-frequency electric and magnetic fields, and lasers. EPA laboratories may use devices or processes which use or generate nonionizing radiation, and as such, radiation safety officers and SHEMP Managers must be familiar with such devices or processes in their laboratory. In addition, they must be aware that devices that produce nonionizing radiation may also use or generate ionizing radiation. For example, lasers, UV, and RF/microwave sources may generate x-rays.

4.3 Lasers

Laser is an acronym for light amplification by stimulated emission of radiation. Lasers come in many shapes and sizes and have many uses as shown in Table C6-4.

Figure C6-6: Electromagnetic Energy Spectrum

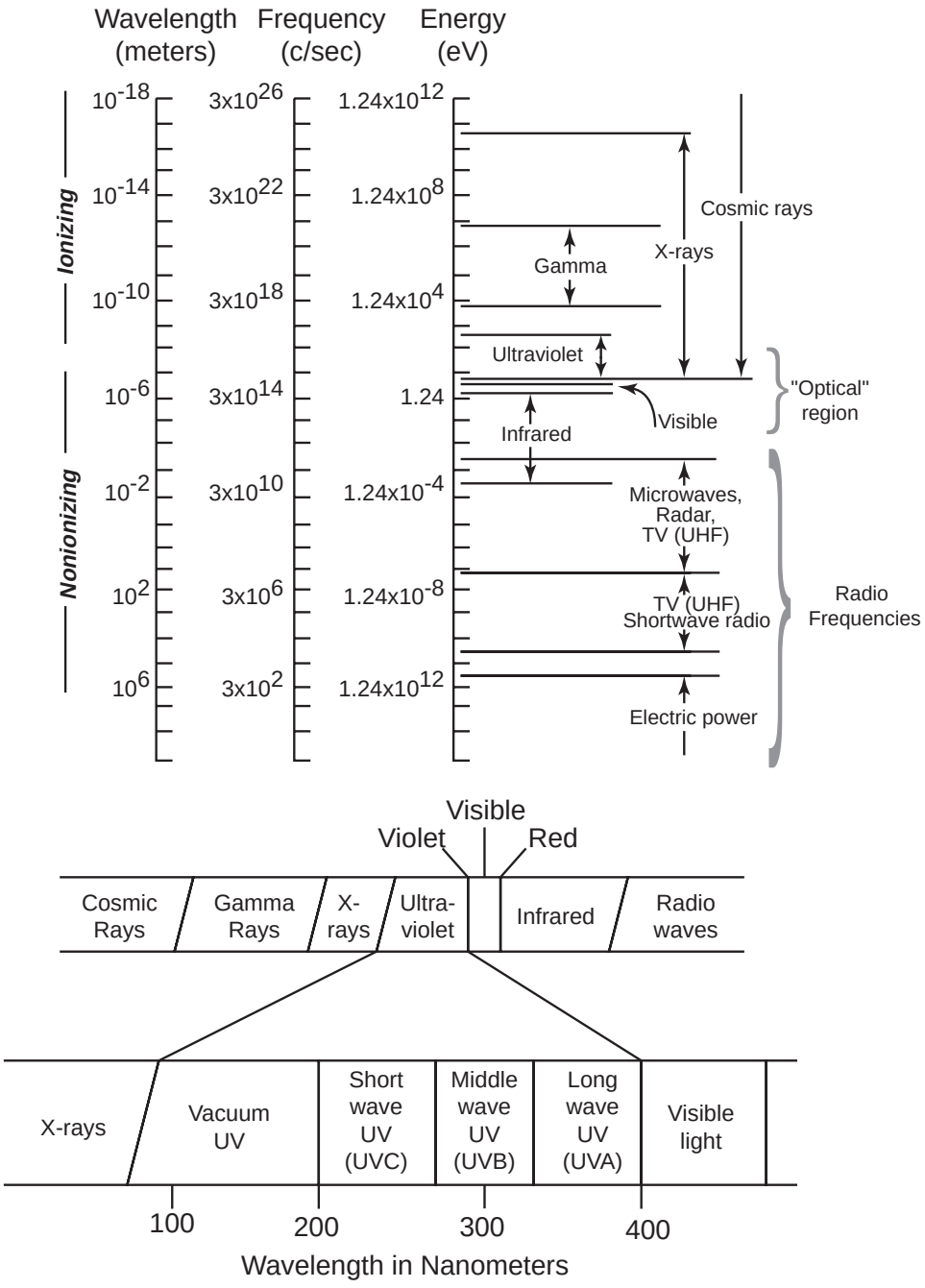


Table C6-4: Major Categories of Laser Use

Alignment	Drilling	Plasma diagnostics
Annealing	Entertainment	Spectroscopy
Balancing	Heat treating	Velocimetry
Biomedical	Holography	Lidar
Cellular research	Information handling	Special photography
Dental	Copying	Scanning microscopy
Diagnostics	Displays	Military
Dermatology	Plate making	Distance ranging
Ophthalmology	Printing	Rifle simulation
Surgery	Reading	Weaponry
Communications	Scanning	Nondestructive training
Construction	Typesetting	Scanning
Alignment	Video display	Sealing
Ranging	Marking	Scribing
Surveying	Laboratory instruments	Soldering
Cutting	Interferometry	Welding
Displays	Metrology	

In general, lasers produce coherent, monochromatic, collimated electromagnetic radiation in the wavelength region of 10 to 10^6 nanometers (nm) and operate a continuous wave (cw) or pulsed mode. Attachment C6-1 lists some common the laser types and their wavelength output based on the lasing medium.

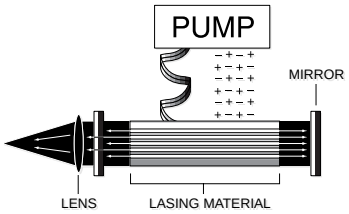
4.3.1 Laser Components

There are three basic components that all lasers have in common:

- An optical cavity that contains the media to be excited, with mirrors to redirect the produced photons back along the same general path

- A pumping system that uses photons from an external source to transfer energy to the media (optical pumping); electrical discharge from within the media (collision pumping); or binding energy released in chemical reactions

- A lasing medium can either be a solid, liquid (dye), gas, or semiconductor. Lasers are commonly designed by the type of lasing material employed. Table C6-5 provides examples of lasing medium.



4.3.2 Laser Classifications

The intent of laser hazard classification is to warn users about the hazards presented by various levels of laser radiation. It also serves as a basis of defining control measures and medical surveillance requirements.

Table C6-5: Examples of Lasing Medium

Solid State	Lasers have lasing material distributed in a solid matrix, e.g., the ruby or neodymium-YAG (yttrium aluminum garnet) lasers. The neodymium-YAG laser emits infrared light at 1.064 micrometers.
Gas	Lasers (helium and helium-neon, HeNe, are the most common gas lasers) have a primary output of a visible red light. CO_2 lasers emit energy in the far infrared, 10.6 micrometers, and are used for cutting hard materials.
Excimer	Excimers (the name is derived from the terms excited and dimers) use reactive gases such as chlorine and fluorine mixed with inert gases such as argon, krypton, or xenon. When electrically stimulated, a pseudomolecule (also known as a dimer) is produced and, when lased, produces light in the ultraviolet range.
Dye	Lasers use complex organic dyes like rhodamine 6G in liquid solution or suspension as lasing media. They are tunable over a broad range of wavelengths.

Lasers and laser systems that are purchased from manufacturers are required, by federal law 21 CFR Part 1000, to be classified and appropriately labeled by the manufacturer. It should be stressed, however, that the classification may change whenever the laser or laser system Lasers is modified to accomplish a given task. Virtually all of the U.S. standards (and of international standards) divide all lasers into four major hazard categories called the laser hazard classifications. The classes are based on a scheme of graded risk pertaining to the ability of a beam to cause biological damage to the eye or skin. Lasers and laser systems are assigned one of four broad Classes (I to IV) depending on the potential for causing biological damage. Attachments C6-1 and C6-2 present a laser evaluation checklist and a summary of these classes.

4.4 Radiation-Generating Devices

A radiation-generating devices is any device capable of producing ionizing radiation when the associated control devices are operated, except devices that produce radiation only by the use of radioactive material. An enclosed system is a RGD that satisfies the requirement that all areas with exposure rates greater than 0.25 mR/hr are enclosed within an interlocked barrier. All other RGD are considered open systems.

They can be classified into one of four categories based on the potential risk of extremity, eye, or whole-body exposure. Attachment C6-3 summarizes the characteristics of these categories and provides typical examples of each.

Examples of RGDs that may be used in EPA laboratories include analytical x-ray equipment, particle accelerators, and electron microscopes. Each are described in the following sections.

4.4.1 Analytical X-ray Equipment

Analytical x-ray equipment is any x-ray equipment used for x-ray diffraction, fluorescence analysis or spectroscopy. For example, x-ray diffractometers consist of an x-ray generator, a goniometer and sample holder, and an x-ray detector such as photographic film or a movable proportional counter. X-ray tubes generate x-rays by bombarding a metal target with high-energy (10 - 100 keV) electrons that knock out core electrons. An electron in an outer shell fills the hole in the inner shell and emits an x-ray photon. X-rays can also be generated by decelerating electrons in a target or a synchrotron ring. These sources produce a continuous spectrum of x-rays and require a crystal monochromator to select a single wavelength.

4.4.2 Electron Microscopes

Electron microscopes are scientific instruments that use a stream of highly energetic electrons to examine objects on a very fine scale. The electrons are accelerated toward the specimen being examined using a positive electric potential. The stream of electrons is confined and focused into a thin, monochromatic beam using metal apertures and magnetic lenses. The beam is focused onto the sample using a magnetic lens. Interactions occur inside the irradiated sample, which affect the electron beam. The effects are detected and transformed into an image.

There are two major types of electron microscopes: transmission and scanning. The transmission electron microscope (TEM) sends a beam of electrons through the specimen. The portion of the beam that is transmitted is projected to a phosphor screen for the user to see.

A scanning electron microscope (SEM) sends a beam of electrons in a grid-like fashion, dwelling on points for a period of time determined by the scan speed. Detection instruments count the number of interactions between the beam and the specimen at dwell points. These interactions are displayed as pixels on a cathode-ray tube (CRT); the more reactions detected, the brighter the pixel.

4.4.3 Particle Accelerators

An accelerator uses electromagnetic fields to speed up particles so that they collide with a target. Detectors surrounding the target record the interaction between the particles and the target. Particles are sped up by moving the electromagnetic field down the accelerator, which moves the particles that are either attracted to, or repelled by, the field.

There are several different design approaches to particle accelerators: arrangement to provide collision of the beam with a fixed target or another beam; shaping the accelerator as a Linac (e.g., linear accelerator), or synchrotron (e.g., circular accelerator). Linear accelerators are used for fixed-target experiments, as injectors to circular accelerators, or as linear collider. Beams from a circular accelerator can be used for colliding-beam experiments or can be extracted from the ring to hit a fixed target.

5.0 Radiation Exposure Hazards

Radiation exposure hazards in EPA laboratories vary depending on the materials and devices that are used. This section presents the hazards to laboratory staff from exposure to ionizing radiation, nonionizing radiation, lasers and radiation-generating machines.

5.1 Ionizing Radiation

Ionizing radiation causes damage to cells, that is primarily nonspecific. Other physical and chemical substances cause the same effects because the body responds the same to certain cell damage regardless of the cause. Radiation passing through living cells will directly ionize or excite atoms and molecules in the cell structure. These changes affect the forces which bind the atoms together into molecules. If the molecule breaks up, some of the parts will be ions which are not chemically stable.

The total effect on cell processes is a function of the dose of radiation. The cell processes will be affected in varying degrees up to cell death. Some damage to the cell may be repaired. This can be accomplished by the action of the cell itself, or by replacement of badly injured cells in a given tissue through mitosis of healthy cells. On the other hand, if the extent of the damage to an organ is quite large, the organ may not be able to repair itself. That is, damaged cells may show confused growth but eventually be unable to divide. Cells may also begin to exhibit uncontrolled growth. Although many factors are important in assessing the total damage, it seems that most cell functions and structures are somewhat impaired by radiation.

5.1.1 Radiosensitivity

Since the cells which make up the tissues of the body differ both in appearance and function, their response to radiation would also differ. This property is known as the radiosensitivity of the cell. Cells which are most active in reproducing themselves, cells which have a high meiotic rate, are more sensitive to radiation. Also, there is evidence that cells are more susceptible to radiation at certain stages of division than at others. Moreover, cells not fully mature will also be more harmed by radiation than mature cells. The second factor which affects radiosensitivity is cell specificity. In the body, bone marrow, lymphoid tissues, and the reproductive organs rank among the most radiosensitive. Muscle, nerve, and bone cells are the least radiosensitive.

5.1.2 Radiation Damage

Damage to somatic cells is limited to the individual, whereas damage to germ cells may result in damage to the offspring of an individual. One may broadly classify biological effects in man as somatic or hereditary. Somatic effects include any and all types of damage which affect only the individual; hereditary effects are those which can be transmitted to a future generation. Thus, damage to the genes of a somatic cell may produce damage to a daughter cell, but this would be a somatic effect, not hereditary. The term genetic damage refers to hereditary effects only when the damage affects the germ line since only then can these effects be transmitted to a future generation.

Somatic Effects

The problem in the study of late effects resulting from exposure to radiation is that the elapsed time may be rather long, thus making it hard to relate the cause to the effect. Since the late effects may be caused by many other agents besides radiation, there can be no positive assignment of the cause in most cases. At best, it can be shown that radiation increases the incidence of these nonspecific injuries.

Cancers

Although scientists understand some of the intra-cellular processes that are initiated or stimulated by radiation and which may eventually result in a cancer, the level of understanding is insufficient at present to enable prediction of the exact outcome in irradiated cells. Since nearly 20% of all deaths in the United States result from cancer, the estimated number of cancers attributable to low-level radiation is only a small fraction of the total number that occur. Furthermore, the cancers that result from radiation have no special features by which they can be distinguished from those produced by other causes. Thus, the probability that cancer will result from a small dose can be estimated only by extrapolation from the increased rates of cancer that have been observed after larger doses, based on assumptions about the dose-incidence relationship at low doses.

Tissue Effects

Among the more prominent acute effects of high radiation doses in tissues are cataracts and sterility. Radiation-induced cataracts are slowly progressive over a period of time, but may stop or even regress. Sterility is an effect which may be either permanent or temporary. In some cases, fertility will return in a few years.

Life-Span

Information on life-shortening effects in man is still inadequate. The effects of long-term, low-level irradiation on longevity cannot be predicted. With the exception of tumor induction, there is no evidence of life-shortening effects.

Growth and Development

Effects on the embryo depend upon the dose as well as the age of the embryo. The younger the embryo, the more it is affected. Here, the results of damage are the same as those caused by other chemical or physical agents. The effects on the fetus are so much more important since minor damage may be amplified into a major anomaly during growth. Relatively high doses can cause death, malformation, mental retardation and impairment of function. Susceptibility for certain cancers appears to be higher during prenatal and childhood periods.

Hereditary Effects

The study of hereditary effects attempts to discover the traits which can be transmitted from generation to generation in a given species. The genes are the determinants of the inherited traits. Any changes or mutation of a gene, which is usually quite stable, can result in an altered trait. Such changes can be produced by radiation, as well as other agents. The study of radiation-induced mutations is thus hampered by the fact that other substances also act to produce the same effects. Since the change is not unique, radiation only serves to increase the frequency of the

effect. Increases in the rate are small even for high doses. Thus, the study requires the use of large numbers of subjects over many generations. In the case of man, the study is very difficult, since large numbers are seldom available and the time between generations is so long. To date, there has been no demonstration of radiation induced mutations in man.

For this reason, much of the present knowledge is based on work with animals. At all doses and dose rates used up to the present, radiation is known to induce mutations in all species studied. Because of this, any increase of radiation to humans is assumed to bring about an increase in the mutation rate. Sometimes the application of animal data to man can result in error. However, in some cases, the effects on some other species are similar enough to those in man. Therefore we prudently limit radiation exposure to keep hereditary effects to a minimum.

5.1.3 Factors Influencing Radiation Effects

The radiation effects in man and animals are usually discussed in terms of total body and partial body irradiation, and with reference to damage to an organ. Because of the importance of some organs in the body, certain damage to these can induce effects in other organs. A number of physical factors are important in the determination of radiation effects:

- Sensitivity of the individual - for a select group, the effects may differ greatly from those in a heterogeneous group
- Nature and type of radiation - some types of radiation are more effective in producing damage
- Absorbed dose - this is a function of the energy absorbed per gram of tissue
- Time distribution or fractionation - a lethal dose given in a short time may not be lethal if protracted over a long time
- Dose distribution - is the total body involved or only a specific organ
- Age at irradiation - response is altered during growth in some systems

The nature, severity and duration of biological effects depend upon the above and other factors. The combination of factors makes the effects on different organs differ with changes in the number of relevant parameters.

5.2 Nonionizing Radiation

The depth of penetration and the sites of absorption of nonionizing radiation depend on the wavelength of the energy. As such, nonionizing radiation hazards vary with the type of radiation.

5.2.1 Eye Effects

Infrared light is transmitted through the cornea and lens of the eye and absorbed primarily by the retina. The visible and infrared portions of the electromagnetic spectrum are referred to as the “Retinal Hazard Region” because they can damage the retina. The amount of hazard from viewing a nonionizing radiation source increases with increased pupil dilation and

duration of the beam. Ultraviolet light is divided into wavelength groupings UV-A, -B and -C. The UV-A wavelengths are most commonly absorbed by the lens of the eye and can cause photochemical damage. The UV-B, UV-C and some infrared wavelengths are absorbed by the cornea of the eye and result in conjunctivitis, milky cornea, and inflammation.

5.2.2 Skin Effects

The layers of the skin that may be affected by nonionizing radiation include the epidermis and dermis. The epidermis absorbs UV-B and UV-C radiation and can blister or show erythema as a result. UV-B radiation is also associated with carcinogenic effects on the skin. The dermis absorbs infrared wavelengths and deep heating of the skin tissue can result.

5.2.3 Other Hazards

Toxic gases and vapors may be created when some nonionizing radiation equipment is used. As such, room ventilation must be adequate to remove reaction and decomposition products that may be hazardous, toxic or infectious.

5.3 Lasers

Staff who use lasers in EPA laboratories may be exposed to both beam and non-beam hazards. Beam hazards pertain to exposure to the eyes or skin from the direct laser beam. Non-beam hazards pertain to a series of hazards that are related to laser use such as collateral radiation, noise, explosion, flammability of enclosures, and more. The following sections discuss these laser exposure hazards.

5.3.1 Beam Hazards

Exposure to laser beams of sufficient intensity can burn skin and eye tissue and cause irreversible damage to the eye. Beam intensity, duration of exposure, and wavelength of the beam are important considerations.

Injury occurs where excessive laser energy is absorbed. Different parts of the eye absorb radiation of different wavelengths.

Eye Effects

Cornea. The cornea is subject to injury from tissue heating because it absorbs optical radiation in the far infrared region of the optical spectrum. Exposures at low intensity in far infrared wavelengths can produce “welder’s flash,”or sunburn of the eye, through a photochemical mechanism.

Lens. The lens absorbs optical radiation in the near UV and middle infrared regions. Overexposure can produce cataracts, the clouding of the lens.

Retina. The retina is a part of the eye that is most susceptible to injury by laser light in the range of 400 to 1,400 nm. The lens focuses all of the laser beam power that passes through the pupil onto a tiny spot on the retina. The fovea is the region of the retina that gives us the ability to see detail. The most severe damage will occur if a high-power laser beam is focused by the lens on the fovea. If the fovea is damaged, there can be an immediate and permanent impairment of vision.

Skin Effects
Although the large surface area of the skin presents more possibilities for exposure than the eye, inadvertent overexposure to the skin is less significant for three reasons:

- The minimum power density where skin injury occurs is much higher than the minimum required to cause retinal injury.
- Skin injury can usually heal whereas retinal injury cannot.
- Loss of vision can be permanently incapacitating, whereas localized skin burns are not.

Low-level irradiance from middle and far UV (200 to < 300 nm) lasers can cause "sunburn" and accelerated skin aging. Skin burns and excessively dry skin can occur from exposure at all regions of the optical spectrum.

5.3.2 Non-Beam Hazards
In addition to exposure to the direct or reflected beam, lasers may present other potential dangers.

Industrial Hygiene
Potential hazards associated with compressed gases, cryogenic materials, toxic and carcinogenic materials, and noise should be considered. Adequate ventilation shall be installed to reduce noxious or potentially hazardous fumes and vapors produced by laser welding, cutting, and other target interactions, to levels below the appropriate threshold limit values (e.g., American Conference of Governmental Industrial Hygienists [ACGIH] threshold limit values [TLVs] or OSHA permissible exposure limits [PELs]).

Photobiological Spectral Domain	Eye Effects	Skin Effects
Ultraviolet C (0.200-0.280 micrometers)	Photokeratitis	• Erythema (sunburn) • Skin Cancer
Ultraviolet Belerated (0.280-0.315 micrometers)	Photokeratitis	• Accelerated skin aging • Increased pigmentation
Ultraviolet A (0.315-0.400 micrometers)	Photochemical UV cataract	• Pigment darkening • Photosensitive reactions
Visible (0.400-0.780 micrometers)	Photochemical and thermal retinal injury	• Pigment darkening • Photosensitive reactions
Infrared A (0.780-1,400 micrometers)	Cataracts, retinal burns, corneal burns, and aqueous flare	• Skin burn
Infrared B (1,400-3,000 micrometers)	Cataracts, retinal burns, corneal burns, and aqueous flare	• Skin burn
Infrared C (3,000-1,000 micrometers)	Corneal burn only	• Skin burn

Explosion
High-pressure arc lamps and filament lamps or laser welding equipment shall be enclosed in housings that can withstand the maximum pressures resulting from lamp explosion or disintegration. The laser target and element of the optical train, which may shatter during laser operation, shall also be enclosed.

Nonbeam optical
This relates to optical beam hazards other than laser beam hazards. Ultraviolet radiation emitted from laser discharge tubes, pumping lamps, and laser welding plasmas shall be suitably shielded to reduce exposure to levels below the ANSI Z136.1 (extended source), OSHA PELs, and/or ACGIH TLVs.

Collateral radiation
Radiation, other than laser radiation, associated with the operation of a laser or laser system (e.g., radio frequency [RF] energy associated with some plasma tubes), as well as x-ray emission associated with the high-voltage power supplies used with excimer lasers, shall be maintained below the applicable protection guides. The appropriate protection guide for RF and microwave energy is that given in the American National Standard "Safety levels with respect to human exposure to radio frequency electromagnetic fields, 300 kHz to 100 GHz," ANSI C95.1; the appropriate protection guides for exposure to x-ray emission is found in the Department of Labor Occupational Safety and Health Standards, 29 CFR Part 1910.96 and the applicable state codes. Lasers and laser systems which, by design, would be expected to generate appreciable levels of collateral radiation, should be monitored.

UV radiation can produce high concentrations of ozone. Low-intensity UV between 200 and 315 nm can cause skin burns. Burns or excessive ozone release can be corrected by proper enclosure and ventilation.

Electrical
The intended application of the laser equipment determines the method of electrical installation and connection of the power supply circuit (for example, conduit versus flexible cord). All equipment shall be installed in accordance with the National Electrical Code and the Occupational Safety and Health Act.

Flammability of laser enclosures
Enclosure of Class IV laser beams and terminations of some focused Class IIIB lasers can result in potential fire hazards if the enclosure materials are exposed to irradiances exceeding 10 W/cm^2. Plastic materials are not precluded as an enclosure material, but their use and potential for flammability and toxic fume release following direct exposure should be considered. Flame-resistant materials and commercially available products specifically designed for laser enclosures should also be considered.

Risk of injury from these other sources must also be controlled in the laser installation.

5.4 RGD Hazards
Hazards associated with RGDs can include exposure to an intense, localized primary x-ray beam and exposure to leakage of diffracted and/or scattered portions of the primary beam. The users of RGDs should be aware that the radiation generated has the potential to be very dangerous.

5.4.1 Analytical X-Ray Machines
Sources of exposure to radiation include the primary beam, leakage of primary beam through cracks in shielding, diffracted beams, as well as radiation gen-

erated by rectifiers in the high voltage power supply. Radiation survey instruments must be available in x-ray laboratories to check shielding and beam conditions. Severe burns can result from exposures of the hands, arms, or eyes to the direct or diffracted beams. Erythema (i.e., reddening of the skin), epilation, and dermatitis are effects from doses ranging from 500 to several thousand rem. The intensities of the primary radiation from the RGDs can be tens of thousand of rem./minute. Doses large enough to cause the skin damage can be reached with very short direct exposures to the primary beam.

5.4.2 Electron Microscopes

Electron microscopes produce x-rays when the primary electron beam or back scattered electrons strike metal parts of the microscope. The shielding provided by the metal casing of the microscope and leaded glass on the viewing ports is usually adequate to ensure that radiation exposure to personnel is kept to a minimum.

5.4.3 Particle Accelerators

Hazards associated with particle accelerators include prompt radiation fields (e.g., primary and secondary radiations) other hazards (e.g., stray radiation, induced radioactivity and skyshine). Each are discussed in the following sections.

Prompt Radiation Fields

Prompt radiation fields consist of the primary beam of particles that are accelerated by the particle accelerator directed and focused into a beam. Exposure to the beam itself presents extreme external hazards. When the beam strikes an object (e.g., a target, target holder or beam stopper), the beam may scatter in the backward direction or produce secondary radiation that may be very penetrating.

Secondary radiation is produced when the primary beam strikes a target or other material. As a result of this interaction, either charged particles are created or electromagnetic radiation is produced. This secondary radiation is often the principle useful output of the machine (e.g., x-rays for radiography and neutrons for activation analysis).

Other Hazards

Other hazards associated with particle accelerators include stray radiation, induced radioactivity and skyshine.

Stray radiation may occur due to misalignment, back-streaming or dark current. If parts of the accelerator are misaligned, a portion of the internal beam may strike the interior of the accelerator and cause stray radiation from an unusual area of the machine. Back-streaming occurs when a stream of particles of opposite charge is released from the primary beam and is accelerated in the opposite direction. Dark current is produced when poor vacuum conditions exist or when accelerator vacuum components are being outgassed.

Induced radioactivity can occur in several ways: activation of targets and other materials, airborne radioactive materials, neutrons. Each are discussed in the following sections:

- *Activation of the Targets and Accelerator.* Activation can occur if the beam strikes any material in the accelerator or if the material is exposed to intense

secondary radiation, it will become radioactive. Radiation from these areas does not become a personnel hazard until the machine is turned off and personnel enter these areas for accelerator maintenance target changes or adjustments. In addition, activation of the cooling water and other cooling media in targets can be hazardous during maintenance work after the accelerator is shut down.

- *Airborne radioactive materials.* Air in an accelerator room can become radioactive if the beam passes through air, radioactive gases produced internally in the targets may escape into the target area or accelerator room as a result of a breach in the containment.

- *Neutrons*. Neutrons are generated in all directions with a high energy component in the forward direction. As the accelerator energy increases, the high energy component becomes more important and is the basis of shielding around accelerators.

Skyshine

When radiation is directed upward and scattered back toward the surface of the earth by collision with nuclei in the air, the process of skyshine occurs. If skyshine occurs, radiation doses farther away from the accelerator room may be higher than in the accelerator room itself. If adequate roof shielding is provided in the accelerator room, this is not a problem.

6.0 Exposure Limits

There are limits set for exposure to radiation in the workplace. This section discusses these limits for ionizing radiation, nonionizing radiation and lasers.

6.1 Ionizing Radiation

It is EPA's policy to protect its employees' health by ensuring that any occupational exposures to ionizing radiation are kept to levels that are ALARA. This is accomplished through a dose limitation system that specifies a limiting yearly numerical value for doses. Also, an action reference level indicates the need for investigation when a predefined interim dose has been incurred. These limiting levels are chosen to be achievable, based on actual dosimetry results for EPA employees, and are well below the established federal limits for radiation workers. Table C6-6 provides a summary of radiation dose limits.

6.1.1 Maximum Permissible Doses

The administrative control level (ACL) is 500 millirem (5 millisievert) total effective dose equivalent and 5,000 millirem (50 millisievert) shallow dose equivalent to the skin or to any extremity in any period of twelve consecutive months. This ACL represents the maximum dose permitted for an individual worker during any 12-month period. Once a worker has reached the ACL, then no further assignments involving tasks with potential radiation exposure may be made for a period of time as determined by the SHEMP Manager in consultation with the RSO. Exceptions to

Table C6-6: Radiation Dose Limits

	NRC	EPA	NCRP
Total Effective Dose Equivalent	5 rem	0.5 rem	
Shallow Dose Equivalent	50 rem	5 rem	
External Dose for the Embryo/Fetus of a Declared Pregnant Woman	0.5 rem	0.5 rem	2-3 rem

the ACL or dose limits applicable to normal work situations may be permitted only as stipulated in SHEM Guide 38. Such exceptions would include imminent danger situations, actions conducted under radiological emergency response plans, or unusual situations where a waiver of the ACL is authorized.

The ACL for EPA laboratory employees is an order of magnitude less than the NRC limit stipulated in 10 CFR 20. Extremity dose limits for EPA employees are also set at one-tenth of the NRC limits; thus, the maximum allowable extremity dose is five rem per year.

6.1.2 NRC Fetal Protection Policy

The NRC Fetal Protection Policy is based on Title VII of the Civil Rights Act of 1964, as amended by the Pregnancy Discrimination Act, which forbids sex-specific fetal-protection policies. In addition, the decision of the Johnson Controls case was very influential. The Supreme Court decision on Johnson Controls stated "[it is inappropriate]... for individual employers to decide whether a woman's reproductive role is more important to herself and her family than her economic role. Congress has left the choice to the woman as hers to make."

The NRC Fetal Protection Policy provides recommendations for fertile women and more restrictive dose limits for declared pregnant women.

Declared Pregnancy

In the revised 10 CFR 20, the NRC states that the external dose limit for the embryo/fetus of a pregnant woman is 500 millirem (5 millisievert) over the entire gestation period (i.e., 9 months). The dose limit of 500 mrem refers to the external exposure of the embryo/fetus. The regulation also cautions that the dose should be delivered at a fairly uniform rate over the entire gestation period and not be delivered in a few large doses.

A "declared" pregnant woman is defined as a "woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception."

As stated in the preamble for Part 20, "it is the fundamental responsibility of the pregnant worker to decide when or whether she will formally declare her condition to her employer..." Having a woman formally declare her condition to her employer derives from legal, not health protection, considerations.

A pregnant woman who wishes to declare her pregnancy should write a memo addressed to her supervisor and send a copy to the RSO or designee. It is important that the RSO or designee is informed of the declaration so that the EPA laboratory can ensure that the 0.5-rem limit is adhered to.

"If a woman chooses not to declare her pregnancy (even if she is physically obviously pregnant!), the licensee will not be required, under the Commission's regulations, to limit her dose to the 0.5 rem limit." Her dose limit would be the occupational limit of 5 rem per year. EPA licensees will maintain the 500 mrem/yr limit, as prescribed for all EPA employees, but will not be required to take any additional precautions for declared pregnant employees.

The ACL for all workers, including pregnant workers (declared or not), will automatically limit EPA workers to the industry accepted limit of 500 millirem (mrem) or 5 millisievert (mSv) per gestation period. Further, the 50 mrem (0.5 mSv) per-quarter for all EPA workers provides an extra margin of safety.

Increased Personal Monitoring

Personal monitoring shall be increased at the time a pregnancy is declared. A thermoluminescent dosimeter (TLD) badge will be exchanged and processed monthly. The TLD service provider shall immediately report a monthly deep dose that exceeds 50 mrem (0.5 mSv) or shallow dose in excess of 500 mrem (5 mSv). A monthly dose that exceeds 50 mrem (0.5 mSv) shall trigger a review to determine the cause of the exposure and whether a change in work assignment is warranted. In addition, when pregnancy is declared, a health physicist should be consulted to ascertain if a bioassay program is necessary.

Because the exposure limit for pregnant employees is the same as for all EPA employees, there is no reason, based on exposure to radiation, to prohibit pregnant employees from performing their normal assignments at a radiation laboratory. If an employee chooses not to declare a pregnancy, she will continue to be protected by the same dose limitations as any other employees. Specific instruction on prenatal exposure risks and the dose limitation program described in this section shall be included in the basic radiation training course.

Internal Dose to Embryo/Fetus

Even more importantly, a fetus can receive an internal dose from radioactive materials deposited in the mother's body (i.e., through inhalation, ingestion, absorption, a puncture wound, etc.). Radioactive materials may readily cross the mother's placental barrier.

Of particular importance is radioiodine. Studies have shown that the fetal thyroid, which may begin to concentrate iodine as early as the 10^{th} week of gestation, may obtain an extremely high dose as the tiny organ concentrates the iodine that is available from the mother's bloodstream. The fetal dose from placental crossover of radioiodine is assumed to be significant after two months.

Based on this information, it is recommended that pregnant females do not perform iodinations. Working with the labeled product should not be a problem.

Regarding maternal internal contamination, some radionuclides are excreted from the body through the urinary pathway. Thus, these nuclides concentrating in the urinary bladder could deliver a significant external dose to the fetus based upon proximity.

Recommendations For Fertile Females
NRC Regulatory Guide 8.13 is an excellent source of information on the biological risks to the embryo/fetus from ionizing radiation.

The National Council on Radiation Protection (NCRP) recommends that a fertile female keep her dose to between 2,000 and 3,000 mrem per year, which averages to 250 mrem per month (i.e., 3,000 divided by 12 months). Assuming that most women would know if they are pregnant by the second month, the 500-mrem limit will not have been exceeded if the woman received 250 mrem/month for those two months.

It is very important that a pregnant female radiation worker continue to use caution and follow all the procedures for minimizing external and internal contamination, and that doses are kept ALARA.

6.1.3 Determining Compliance with the ACL

The EPA ACL of 500 mrem (5 mSv) per year is the sum of the effective dose equivalent due to all types of occupational radiation exposures received by the employee. Therefore, the sum of the deep-dose equivalent (due to external exposures), the internal dose due to radionuclides other than radon and its progeny given by the CEDE, and the internal exposure due to radon given in terms of WLM, must not exceed 500 mrem (5 mSv) per year. A method of summing these doses, called the "ratio rule," can be used to confirm that the ACL has not been exceeded. The ratio rule is computed as follows:

$$\frac{\text{Deep dose (mrem)}}{500\ \text{(mrem)}} + \frac{\text{CEDE (mrem)}}{500\ \text{(mrem)}} + \frac{\text{Rn-222 Exposure (WLM)}}{1\ \text{(WLM)}} \leq 1.0$$

If the sum of the ratios is less than 1.0, compliance with the ACL has been achieved.

6.2 Nonionizing Radiation

Exposure limits to nonionizing radiation are published by various organizations, depending on the type of radiation as follows:

- The American Conference of Governmental Industrial Hygienists (ACGIH) has adopted a Threshold Limit Value (TLV) system for static and other subradio-frequency electric field in their "Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices."

- The International Commission on Nonionizing Radiation Protection (ICNRP) has issued guidance for staff working with steady magnetic fields.

- The Institute of Electrical and Electronic Engineers (IEEE) has published the "American National Standard Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3 kHz to 300 GHz," as IEEE/ANSI C95.1-1991.

The following sections provide a summary of the ACGIH TLVs for electromagnetic/microwave radiation and ultraviolet radiation.

6.2.1 Electromagnetic/Microwave Radiation

Guidelines for exposure to sources that are not confined in a shielded chamber are published as ACGIH TLVs. Table C6-7 summarizes these limits in terms of electric field strength in volts per meter (V/m) and magnetic field strength in amperes per meter (A/m), for a range of frequencies.

For frequencies below 30 kHz, the electric field strength should not exceed:

Frequency (f)	Electric Field Strength
0 Hz - 100 Hz	25 kV/m
100 Hz - 4 kHz	(2.5 x 106/f) V/m
4 kHz - 30 kHz	625 V/m

For frequencies below 30 kHz, the magnetic field strength should not exceed:

Frequency (f)	Magnetic Field Strength
1 Hz - 300 Hz	60/f mT
300 Hz - 30 kHz	0.2 mT

6.2.2 Ultraviolet Radiation

The total intensity of UV light from lamps and reflecting surfaces should not exceed the levels specified in the ACGIH "Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices." Table C6-8 summarizes these limits in terms of effective irradiance in microwatts per square centimeter (mW/cm^2) for a series of exposure durations per day.

6.3 Laser Exposure Limits

The maximum permissible exposure (MPE) is the maximum level of laser radiation that staff can be exposed to without adverse biological effects to the eye or skin. There are three factors in determining the MPE for lasers: wavelength of laser light, energy involved in the exposure, duration of exposure. The MPE values for eye and skin are listed for various combinations of wavelength and exposure duration in the ANSI Standard Z136.1-1993. There are two measurements around the laser that can be used to determine if the MPE is exceeded.

The nominal ocular hazard distance (NOHD) is the distance along the axis of the direct laser beam to the human eye. Beyond this distance, the MPE of the laser is not exceeded. The nominal hazard zone (NHZ) for lasers is the area where radiation is direct, reflected or scattered so that

Table C6-7: Exposure Guidelines for Electromagnetic/Microwave Radiation

Frequency (f)	RMS Electric Field Strength (V/m)	RMS Magnetic Field Strength (A/m)
30 kHz - 100 kHz	614	163
100 kHz - 3 MHZ	614	16.3/f
3 MHZ - 30 MHZ	1842/f	16.3/f
30 MHZ - 100 MHZ	61.4	16.3/f
100 MHZ - 300 MHZ	61.4	0.163

Table C6-8: Exposure Guidelines for Ultraviolet Radiation

Exposure Duration Per Day	Effective Irradiance ($\mu W/cm^2$)
8 Hours	0.1
4 Hours	0.2
2 Hours	0.4
1 Hour	0.8
30 Minutes	1.7
15 Minutes	3.3
10 Minutes	5
5 Minutes	10
1 Minute	50
30 Seconds	100
10 Seconds	300
1 Second	3000
0.5 Second	6000
0.1 Second	30000

the MPE for the laser would be exceeded. Control measures are typically not needed outside the NHZ.

7.0 Program Administration

Program administration for radiation safety includes: exposure monitoring, medical surveillance, posting and labeling, training, recordkeeping, and program maintenance. Each are discussed in the following sections.

7.1 Exposure Monitoring

Personnel health surveillance involves the use of dosimetry and bioassay to determine occupational exposures. This information is then reported to all workers who participate in the monitoring and dosimetry program.

7.1.1 Types of Personal Dosimetry

Personal monitoring using dosimetry is conducted to ensure that doses during occupational exposure do not exceed annual dose limits. It is important to note that dosimeters do not prevent staff from being exposed. They merely give an idea as to how much and what kind of radiation the laboratory staff has been exposed to.

There are two types of dosimeters that are used to monitor external radiation exposure: film badges and thermoluminescent dosimeters (TLDs).

Film Badges

Film badges are personal monitoring devices designed to be worn by an individual to measure the amount of exposure received. They consist of a piece of photographic film in a light-tight wrapper inserted into a holder.

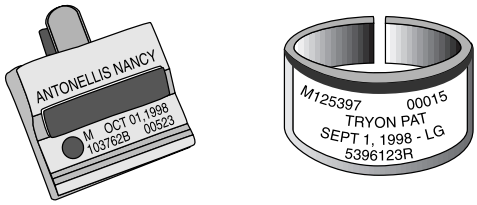
The film holder contains filters (e.g., one each of plastic, aluminum, and lead) that help to determine the type and energy of the radiation to which the film was exposed.

Energetic beta particles and low-energy gamma rays can only be seen behind the open window where there is no filter. High-energy gamma rays will expose the film behind the thin lead filter. Thus, the density of the exposed film is proportional to the radiation energy imparted to the film.

The only requirement for use of film badges is that the radiation be able to penetrate the paper wrapper of the film (i.e., for betas with energy > 250 keV, and any X-ray or gamma radiation).

Thermoluminescent Dosimeters

TLDs consist of a crystalline semiconductor (usually LiF) which will emit light after being heated if it has previously been exposed to radiation.



When the TLD absorbs energy from radiation, the atoms in the crystal become excited and electrons are raised to a metastable state; that is, to a higher energy level. These excited electrons stay in the metastable state until they are heated, causing the excited electrons to return to their normal states. When this happens, light is emitted and detected by a photomultiplier tube. The amount of light emitted is proportional to the number of excited electrons, which is proportional to the amount of energy absorbed and thus proportional to the dose to the TLD.

7.1.2 External Radiation Exposure Measurement

All EPA laboratory workers who routinely work with sources of ionizing radiation while conducting their duties must be assigned a TLD badge. The TLD badge must be worn at all times while in radiological areas. When not in use, the dosimeter must be stored in a controlled environment to prevent damage and inadvertent exposure. An acceptable practice is to provide a TLD badge board to which the TLDs can be secured, along with control badges, when not in use. The badge board should be located in an office area containing no radiation sources, samples, or machines that produce radiation or use radioactive materials. Other practices can be implemented by the RSO if they provide adequate assurance that the integrity of the badge will be maintained during periods when they are not in use.

EPA laboratory workers are exempt from the TLD badge requirement only when all on-site sources of ionizing radiation are limited to sealed sources used in analytical instruments. This stipulation is based on situations where the TLD badge is not sensitive to the radiation emitted by the radionuclides contained in these sealed sources. However, the RSO has the authority to require TLD badges to be worn in the laboratory on a case-by-case basis.

The use of extremity dosimeters, designed to be worn on the wrist or fingers, is recommended for personnel handling substantial amounts of radioactive material (above 0.1 millicurie). If used, such extremity dosimeters are to be worn *in addition to* the standard whole-body TLD. Exposure detected by the extremity TLDs is considered to be shallow-dose equivalent. This combination of TLD badges serves to distinguish a critical organ dose from that of the hands.

Radiation exposure monitoring for laboratory visitors and guests shall be performed in accordance with the requirements provided in the SHEM Guide 38. In instances where visitors or guests may be at risk of exposure to ionizing radiation at levels that are significantly above normal background, the RSO may elect to require the visitor or guest to wear a dosimeter or be monitored for internal radiation exposure while visiting specified work areas.

Additionally, a direct-reading pocket dosimeter(s) may be issued, at the RSO's discretion.

7.1.3 Bioassay Measurements

Internal radiation exposure results from the ingestion, injection, inhalation, or absorption of radionuclides into the body. Internal exposure monitoring and dose assessment of personnel are considerably more difficult and less precise than external exposure measurements. This is due to the highly complex variables that govern intake; distribution; retention and elimination of radionuclides by various tissues/organs of the body; and evaluation of various absorbed doses and dose equivalent quantities.

Internal exposure monitoring is routinely accomplished by performing work-area monitoring of respirable airborne radioactivity, along with calculations to estimate probable exposure. When appropriate, bioassay techniques, together with established human biokinetic models, may be used as adjuncts in the assessment of internal dose. The principal bioassay techniques used are urinalysis, fecal analysis, and whole-body/lung counting.

When there is reason to believe that a significant radionuclide intake may have occurred, an immediate response is required. If the required expertise is not available at the laboratory, the RSO should immediately contact a health physicist to provide appropriate action and follow-up procedures, and to determine the need for an internal dose assessment and recommend appropriate bioassay procedures to confirm and assess the possible exposure. Factors to consider include the radionuclide(s) involved, quantities of the radionuclide(s), chemical and physical form of the radionuclide(s), route of intake, duration of exposure, and the time elapsed

since the potential exposure occurred (details are given in a separate guidance document for internal exposure monitoring).

Baseline Radionuclide-Specific Analysis
The RSO, in consultation with the SHEMP Manager, shall determine which enrollees require an initial baseline radionuclide-specific analysis. Such decisions should be based on the nature of the worker's radiation exposure history and/or the nature of anticipated laboratory work assignments. The results of a baseline analysis are to be maintained by the facility, and must also be made available to the central dosimetry recording system at headquarters within the calendar year.

Enrollees who receive a baseline radionuclide-specific analysis at any point during their participation in this monitoring and dosimetry program should also receive a bioassay at the time of termination from this program. The exit bioassay should include an assessment of those radionuclides to which a worker may have been exposed, in addition to select radionuclides included in the initial or subsequent bioassays.

Urinalysis
Urine samples determine the potential uptakes of radionuclides that are absorbed by the gut or are transferred from the lungs to the bloodstream. Urine samples collected for personnel monitoring consist either of a single voiding or a composite of all voidings that occur over a 24-hour period. Collection of urine samples shall be coordinated by the RSO.

Fecal Analysis
Fecal analyses are not performed routinely, but only when urine sampling is inadequate or inappropriate for quantifying the intake or dose of the radionuclide in its chemical form of interest (i.e., the radionuclide is not excreted via the urinary route). Plutonium oxide, because of its insolubility in the lung (solubility class Y) and small absorption potential in the gastrointestinal tract, is an example. A fecal analysis may also be performed in the case of an accidental exposure, when the health physicist determines that it is necessary to properly assess the exposure. Sample collection and analysis is coordinated by the RSO.

In-Vivo Monitoring
In-vivo monitoring (whole-body or partial-body counting) is the detection and quantification of radioactive materials in an individual's body by directly measuring the photons emitted from the body or from organs within the body. Thus, it is sensitive only to photon-emitting radionuclides. Whole-body counting is often employed after a potential contaminating event or as a follow-up to a positive result of another bioassay procedure. The logistics of obtaining a whole-body count measurement are coordinated by the RSO. Baseline whole-body counts can be required by the RSO on a case-by-case basis (e.g., consideration of the individual's work history prior to EPA employment). In this case, however, it should be possible to obtain the employee's exit whole-body results from the previous employer.

Nasal Smears
Nasal smears (i.e., wipes) may be required from individuals who work in areas where there is potential for inhalation of airborne radioactive particulates. Nasal smears may be required from individuals after respirator use to check for positive evidence of ineffective respiratory protection . If the analysis of nasal smears is positive, prompt decontamination measures, dose mitigation measures (e.g., forcing fluids), or additional bioassay procedures (e.g., urine/ fecal analysis, whole-body counting) may be initiated by the RSO. A negative indication on nasal smears should not be considered as conclusive evidence that an intake of radioactive materials has not occurred.

7.1.4 RGD Exposure Monitoring

All staff using RGDs should wear personal dosimetry at all times. Dosimeters should be provided to staff working with equipment having an open-beam configuration without a safety device; personnel maintaining equipment if the maintenance procedures requiring the presence of a primary beam when any local component in system is disassembled or removed.

The beams of x-ray diffraction units are often well collimated and may well be as small as 0.3 mm in diameter. This makes recording occupational exposures with body or ring dosimetry badges difficult. However, dosimetry badges may show exposures indicating the first signs that there is a problem with the unit. As such, staff must wear a film badge and ring badge when using the equipment. Dosimetry is typically not issued for use with electron microscopes or other enclosed systems.

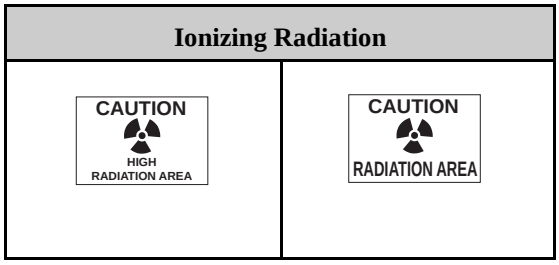
7.2 Medical Surveillance

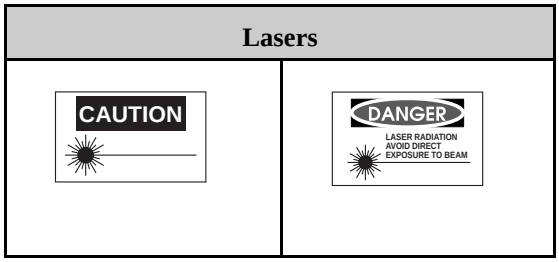
Individuals who occupationally encounter potential health hazards must undergo medical surveillance examinations to determine, to the extent possible, the degree to which such hazards alter their health status. The medical monitoring requirements for entering a radiological area are no different than requirements for entering any hazardous materials area.

More information on medical monitoring is included in Chapter C2.

7.3 Posting and Labeling

Access to any area or laboratory where there are radiation hazards must be clearly posted with a conspicuous sign bearing words that describe the nature of the hazard. In addition, access to these areas must be controlled. Following are several examples of posting that may be seen in these areas:





RGDs	
	

Additional information, as appropriate, may be provided on or near the signs to make individuals aware of potential radiation exposures and to minimize the exposures.

7.4 Training

In every facility, the training requirements of different groups of employees will vary depending on several factors.

- The potential for radiation exposure of employees can usually be estimated before the work starts. The degree and nature of the potential exposure, such as from airborne radioactivity, surface contamination, or radiation from devices or sources, will also determine the nature and depth of the training program.

- Some tasks are more complicated than others and require considerably more training to ensure that the job can be completed safely and competently, and that the associated radiation exposure can be maintained ALARA.

- Several other factors that may influence and modify training needs are:

  — Personnel who are directly and continuously supervised will normally need less training than those who work independently or who have infrequent supervision.

  — Individuals who are responsible for the supervision of others will usually require more training.

  — Individuals who have received previous training may not require additional training. However, care must be taken to ensure that the previous training is current and applicable to the needs of the employee's present position.

  — Individuals who have extraordinary personal concerns about ionizing radiation may need special attention.

The specific requirements for radiation safety training are covered in Chapter C3 of this manual.

7.5 Recordkeeping

EPA worker radiation dose and exposure records are generated and maintained for the purpose of evaluating compliance with all applicable dose limits and monitoring and reporting requirements. Regions, program offices, and laboratories will retain all dosimetry data for their workers while enrolled. Additionally, a computer-based radiation dosimetry recording system at headquarters serves as the centralized data repository and recordkeeping resource. Individual worker dosimetry data, maintained on this system for the duration of active enrollment plus 30

years, are available only to the respective authorized SHEMP Managers, RSOs, and other duly authorized personnel, but can be requested in writing by the worker.

All workers participating in the monitoring and dosimetry program shall be routinely notified in writing of their radiation exposure, regardless of their exposure dose. At a minimum, such notification shall be furnished on a quarterly basis. Dose and exposure records are also furnished to individuals on request, as required by 10 CFR Part 19.13, "Notification and Reports to Individuals." All monitoring and dosimetry records will be maintained in a manner consistent with that of other confidential records, and in accordance with Privacy Act restrictions. These records shall be maintained by the Agency for a period of not less than 30 years following a worker's separation from EPA employment. Post-employment radiation exposure record requests should be directed to the responsible SHEMP Manager (or RSO in the absence of a SHEMP Manager) of the region or facility where the last dosimetry reports were received.

7.6 Program Maintenance

To maintain an effective radiation protection program, it must be evaluated and updated periodically.

7.6.1 Evaluation of Program Effectiveness

Audits are an integral part of the ongoing operation of a radiation safety program. Appropriate audits of radiation source usage can provide an evaluation of the radiation safety program, pinpoint deficiencies, and indicate when users are in need of retraining. Audits can also indicate whether or not alarm signals and access controls are operating properly. Audits should also indicate the adequacy of required postings such as signs, labels, notices to employees, copies of licenses, and inspection reports.

7.6.2 Periodic Program Update

The radiation protection program should be reviewed and updated annually or more frequently if there have been major changes in program emphasis, reorganization, or significant staff turnovers.

8.0 Work Practice Controls

Work practice controls as part of the radiation safety program include: acquisition of radioactive material or RGDs, packaging and shipment of materials, receipt of materials, area surveys and monitoring, and protective equipment and clothing. Each are discussed in the following sections.

8.1 Acquisition of Radioactive Material or RGDs

Acquisition of radioactive material encompasses all of the factors involved in obtaining radioactive materials for use in a laboratory. The material must be licensed and of a quantity that will not exceed licensed quantities; the use must be reviewed and approved; and the material must be ordered, shipped, and received through proper channels and by following appropriate procedures.

8.1.1 Licensed Types and Quantities

Each EPA laboratory has its own radioactive materials license(s) issued either from the NRC or the NRC Agreement State agency. The quantities of licensed radioactive material listed on the license represent maximum allowable inventory quantities. Therefore, radioactive material inventory must be consulted prior to the approval of a new radioactive material authorization to ensure that maximum licensed quantities are not exceeded.

8.1.2 Approval System

An authorization system is used to maintain control over the use of radioactive material. Under this system, staff members who are technically qualified by training and experience to use radioactive material in conducting an experiment must apply for authorization to use radioactive materials. Once the authorization form is approved by the RSO, authorization of radioactive material use will be granted for a finite period of time, typically lasting one year. During this year, the principal investigator has the responsibility of ensuring that all work done is in accordance with requirements specified in the authorization form as well as any amendments made by the RSO and/or the radiation safety committee. Prior to expiration of the authorization, the RSO will notify the principal investigator in writing. If a written request for extension is received, the RSO will then either extend the authorization for an additional period of one year or request additional information.

8.1.3 Purchasing Materials and Equipment

All purchase orders for radioactive materials must be approved by the RSO to properly maintain an inventory of radionuclides at the laboratory. Updates to the inventory must be made regularly to include new or deleted isotopes. Employees must inform the RSO of expected changes in the source inventory. The source inventory includes D number, radionuclide, date of entry, specific activity (e.g., microcurie [mCi] per milliliter [l], mCi per gram [g]), total amount (e.g., milliliters, grams), location (e.g., room number), half-life, and any comment. An annual audit is performed by the RSO to update and correct any discrepancies in the laboratory's inventory of radionuclides.

The procedure for procuring radionuclides is outlined in Figure C6-7.

8.2 Packaging and Shipment of Materials

The RSO will package all radioactive materials for shipment off-site in compliance with the applicable requirements stated in 10 CFR Part 71, "Packaging and Transportation of Radioactive Materials," and 49 CFR Part 173 Subpart I, "Radioactive Materials." All transfers of source and by-product material or radioactive waste shipments will also be performed by the RSO.

A copy of the receiving facility's license (state or federal) or statement that indicates authority to possess the material must be on file at the laboratory prior

Figure C6-7: Radioactive Material Procurement Procedure

to shipment. Refer to Chapter C14 of this manual for more information on radioactive waste management.

8.3 Receipt of Materials and Equipment

Samples can be received only at a designated loading dock area, which should be close to the sample preparation area. Samples brought to any other location by a carrier must be redirected to the appropriate loading dock. Samples are never accepted in the lobby.

All packages labeled as follows require immediate notification of the RSO or the alternate RSO:

For packages received during normal working hours, radiological surveys must be performed as soon as practical after receipt of the package, but not later than three hours after the package is received at the licensee's facility. For packages received outside of normal working hours, the survey must be performed no later than three hours from the beginning of the next workday.

In the event that the RSO and alternate RSO are unavailable, individuals designated in the laboratory NRC license (maintained by the RSO and the Laboratory Director) as authorized users of radioactive materials and/or their supervisors, can be consulted for assistance.

A sample packing slip or manifest is required and must be presented at the time of receipt, and the approximate activity of the shipment should be compared to a list of acceptable quantities. If the total activity of the shipment exceeds any of the package limits, the RSO or alternate RSO should be called prior to acceptance of the package from the carrier unless clearance has previously been obtained for the samples. As an example, acceptable package limits approved by NRC for the National Air and Radiation Environmental Laboratory (NAREL) are listed in Attachment C6-4.

Packages suspected to contain leaking sample containers should be placed in plastic bags and/or on plastic trays as

soon as practical before entering the sample preparation area. The RSO or alternate RSO must be notified immediately for assistance.

8.4 Area Surveys and Monitoring

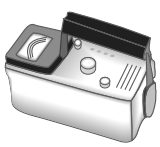
Surveys and monitoring are performed to identify radioactive contamination in the laboratory. This is accomplished using various types of instrumentation such as hand-held survey instruments and liquid scintillation counting.

8.4.1 Hand-Held Survey Instruments

External radiation exposure in laboratory areas is monitored by conducting radiation surveys. Radiation surveys are conducted using Geiger-Mueller (GM) detectors, ionization chambers, micro-R meters, boron trifluoride (BF_3) neutron counters, and alpha scintillation probes, as appropriate. The RSO, or an appropriately qualified EPA worker approved by the RSO with the concurrence of the Laboratory Director, shall perform these surveys.

The majority of surveys are performed to measure beta/gamma exposures (except for low-energy beta particles such as from tritium). Instruments commonly used for this purpose include the following:

- Eberline Model HP-270 and Ludlum Model 14 (both using GM detectors)
- Ludlum Model-19 MicroR meter (sodium iodide detector)
- Victoreen Model 450P (ion chamber)



Although these instruments are commonly regarded as industry standards, their listing should not be considered as an endorsement by the EPA.

Each individual is responsible for monitoring his/her person, clothing, and shoes with the appropriate (beta/gamma and/or alpha-sensitive) hand-held survey instrument before leaving an area if there is a potential for contamination. The RSO (or alternate) must be notified immediately if contamination is detected, and decontamination measures should be promptly initiated.

8.4.2 Survey Instrumentation

GM pancake probes (with an active surface area of about 16 cm^2), calibrated with National Institute of Standards and Technology (NIST) traceable standards, are used to measure surface contamination for beta/gamma activity *(**Note:** GM pancake probes can not detect low-energy betas such as those from tritium)*. The counts per minute (cpm) measured by the probe are converted to disintegrations per minute (dpm) per 100 cm^2 by using the appropriate efficiency (e.g., cpm/dpm) and geometry (active probe area/100 cm^2) factors. Similarly, alpha surface contamination is monitored using an alpha-scintillation probe of known active area and calibrated using NIST traceable standards. Monitoring with both types of probes should be conducted holding the probe within 0.5 cm of the surface, with a scan speed of no greater than one probe width per second.

When a contamination survey is conducted in a potentially contaminated area, care must be taken to prevent contamination of the instrument and detector. However,

when surveying for alpha or beta activity, the sensitive portion of the detector must be uncovered. Although the surveyor should always take care not to touch even a covered detector to a potentially contaminated surface, special care must be exercised when using a probe with an uncovered detector surface.

Use of Survey Instruments
Only EPA laboratory staff members trained in the use of survey instruments are to be allowed to use this equipment. As a minimum, training shall consist of a lecture on the use of the instrument, the meaning of measurements, and its proper handling.

During regular use, battery checks for portable monitoring equipment are necessary to ensure that the battery voltage is high enough to permit correct measurements. A check source, attached to the instrument base, is used to verify proper response of the meter to radiation.

Each instrument contains an audible response ("clicking" sounds) and a visual indicator to alert the user to the presence of radioactive contamination.

Slowly scan with the probe held within about one-half inch from the surface (at a speed no greater than 5 cm/sec).

Calibration and Maintenance
Only instruments with a current calibration label are to be used for conducting surveys. Instruments suspected of providing incorrect measurements should be brought to the attention of radiation safety staff.

Survey instruments in use are to be calibrated at least annually and after instrument repair. The current calibration label showing the date the instrument is due for calibration is attached to the instrument. Calibration and repair should be performed by an approved calibration laboratory. Only those organizations or individuals duly authorized and licensed by the NRC are allowed to perform such calibrations.

8.4.3 Liquid Scintillation Counting

Counting for beta radiation from radioisotopes such as Carbon-14, Tritium (H-3), Sulfur-35, and Phosphorus-33 is usually done with a liquid scintillation counter. Gamma radiation such as from Iodine-125 and Chromium-51 can be measured with a liquid scintillation or gamma counter.

Mode of Operation
Liquid scintillation involves the detection and monitoring of radioactive decay. The radioactive sample to be counted is combined with a "scintillation cocktail" which usually contains a solvent, an emulsifier, and a fluor. This cocktail serves to convert the energy of the particle emitted during the radioactive decay process into light, which is detected by the liquid scintillation counter. A liquid scintillation counter is capable of measuring alpha particles, beta particles, positrons, auger electrons, conversion electrons, and Compton electrons.

Quenching
The liquid scintillation response is a direct relationship between the radioactivity of the sample and the amount of light being emitted from the vial. In practice, a number of factors act to reduce the amount of light being emitted. This phenomenon is

referred to as "quenching," and a sample in which it occurs is said to be "quenched." Quenching causes two effects:

- A reduction in the measured counts or cpm of the sample (lower efficiency)
- A shift of the pulse-height spectrum to lower channel numbers

The two major types of quench are chemical and color.

- Chemical quench is caused by a variety of compounds such as oxygen, water, emulsifiers used in aqueous cocktails, alcohols, etc. Some chemicals are weak quenching agents (e.g., water and alcohol), and several milliliters have little effect on the cpm recorded. Others are very strong quenching agents (e.g., phenol and acetone) and microliter quantities can greatly reduce the cpm. Chemical quench interferes with the transfer of energy from the radioactive decay to the solvent, transfer from the solvent to solvent molecules, or transfer from solvent to fluor. The result is less light produced, so fewer cpm recorded.

- Color quench is caused by the introduction of color from the sample (e.g., hemoglobin or chlorophyll). The light emitted by the fluor is absorbed by the colored solution and does not reach the photomultiplier tubes. The amount of absorption depends on the concentration and color of the quench agent. Blue solutions quench very little, whereas yellow solutions quench very heavily. The end result of quench, whether it is color or chemical, is less light to the phototubes, and therefore, fewer cpm recorded by the instrument.

Counting Efficiency

All samples prepared in the laboratory are quenched to some degree. Therefore, in order to express the data in units that allow accurate comparison, the data must be converted from cpm to a value that correctly reflects the disintegrations that actually occurred in the sample. This value is disintegrations per minute, or dpm. The ratio of cpm to dpm is known as the counting efficiency.

Once the cpm has been obtained by counting, the dpm can be calculated if the counting efficiency is known. Counting efficiencies are normally determined from a quench curve set up in the liquid scintillation instrument prior to beginning to count the experimental samples. The counting efficiency can also be determined by analyzing known standards and comparing the count rate with known dpm values.

Samples may sometimes record a "false positive," observed in the first (H-3) channel, from chemiluminescence (i.e., light emission not originating from radioactive decay).

8.4.4 Contamination Surveys

Laboratories and equipment could become contaminated when liquids and powders that are labeled with radioisotopes are used. It is important that such contamination of surfaces be identified immediately to prevent its spread to other parts of the laboratory and especially to areas outside of the laboratory.

The areas and types of materials surveyed should include: benchtops; sinks; hoods; balances; telephones; door knobs; non-radioactive waste cans; the floor adjacent to these items as well as traffic areas; protective clothing; and hands and shoes.

Survey Frequency

Laboratories using radionuclides must be surveyed at least semiannually by the RSO; however, this should in no way be considered a substitute for routine day-to-day monitoring by personnel working in the laboratories. Laboratory personnel are responsible for routine monitoring of bench tops, fume-hood surfaces, glassware, equipment, tools, etc., in their own work area.

Survey Records

The RSO shall have a floor plan of each laboratory using radionuclides. During the semiannual survey of each lab, the RSO will record all smear locations, dose rates, and any other pertinent radiological information on the survey form. A sample radiological survey form with a laboratory floor plan is shown in Attachment C6-5. These must be retained in the RSO's files for at least three years, as required by 10 CFR Part 20.2103.

During the semiannual monitoring process, the RSO will have an opportunity to observe various laboratory operations and conditions, such as routine personnel practices, refrigerator contents (e.g., presence of any food or drinks), complete and current disposal/receipt records, and isotope storage areas.

The RSO shall direct any changes or decontamination necessary as a result of the survey, and the personnel involved will be responsible for any required action. In addition to the routine semiannual monitoring, the RSO will also perform special monitoring tasks, such as taking necessary air samples and checking hoods and drains for radioactivity prior to repair.

Wipe Testing

An estimate of the amount of removable surface contamination per 100 cm^2 is also required. This is determined by wiping the suspected area with dry filter or soft absorbent paper (smear) using moderate pressure, and assessing the amount of radioactive material on the smear with an appropriate instrument of known efficiency. Dry smears are not appropriate for tritium. However, smears to detect removable alpha contamination must be dry, as moisture will attenuate the alpha particles and lead to an erroneous reading. When removable contamination is found on objects having a surface area less than 100 cm^2, the activity per unit area should be based on the actual area, and the entire surface should be wiped.

Smears are analyzed using a calibrated low-background proportional counter or a scaler with an alpha scintillation detector to evaluate the gross alpha activity, or a GM detector to measure the gross beta/gamma activity. Measurement of low-energy beta emitters such as H-3 and C-14 must be performed by liquid scintillation analysis.

Contamination Action Levels
Contamination action levels are levels of contamination found that should be cleaned up. The action level for contamination surveys is 200 dpm/100 cm^2 in all areas (removable).

Surface contamination, fixed plus removable, can be measured with a hand-held survey instrument that measures the appropriate type of radiation. The results are reported in units of dpm/100 cm^2. The average dpm/100 cm^2 is obtained by measuring an area no larger than a square meter. For an object with surface area less than 100 cm^2, the dpm is determined for the total surface of the object.

Survey Records
A permanent record will be kept of all survey results. The record should include the following information:

- Location, date, and identification of equipment used, including the serial number and pertinent counting efficiencies
- Name of staff conducting the survey
- Drawing of area surveyed, identifying relevant features such as active storage areas, active waste areas, etc.
- Measured exposure rates, keyed to location on the drawing, marking rates that require corrective action
- Detected contamination levels, keyed to locations on the drawing
- Corrective action taken in the case of contamination or excessive exposure rates, reduced contamination or exposure rates after correction action, and any appropriate comments.

Personal Protective Equipment
Personnel performing contamination surveys must wear adequate protective clothing (including but not limited to laboratory coats, safety glasses, and gloves) while performing the survey. The RSO can require the surveyor to wear Level C protection when surveying areas where there is a potential for airborne contamination. Refer to Chapter E of this manual for more information on personal protective clothing and equipment.

Air Sampling
There may be instances when air samples are required to detect and evaluate airborne radioactive material at laboratory work locations, to assess the control of airborne radioactive material in the workplace, and to determine the need for respiratory protection in conjunction with EPA's ALARA program. Air particulate samples may be required:

- In occupied surface-contaminated areas
- During work that may cause airborne radioactivity
- When opening a container that might release radioactivity to the atmosphere
- Whenever airborne radioactivity is observed or suspected
- Whenever requested and justified by a project manager, the branch chief, the RSO or SHEMP Manager

Adequate operable air sampling equipment must be maintained by the laboratory RSO and/or the SHEMP Manager at all times. Refer to Chapter C10 of this manual for information on radionuclide emissions to the air.

8.4.5 Surveys of RGDs

RGDs should be surveyed before resuming routine operations any time that the RGD or procedures for its use are changed such that the radiation output may be increased in intensity, penetration or distribution. The areas adjacent to the installation, including above and below, if occupiable, should be surveyed as well. Surveys should be performed as follows:

- During the performance of maintenance and alignment procedures if the procedures require the presence of a primary beam
- When any component in the system is disassembled or removed
- Any time an inspection of the components in the system reveals an abnormal condition
- Whenever personal dosimeters or surveys show a significant increase over a previous monitoring period or are approaching administrative limits
- After any modification

A ratemeter with a scintillation detector such as a sodium-iodide crystal can be used to detect leakage from an x-ray unit. However, a ratemeter can exhibit a large variation in response with x-ray energy, and is not appropriate for quantitative assessment of radiation leakage levels. To assess levels of leakage, a survey instrument that has been calibrated to the x-ray energies that might be encountered should be used (e.g., hand-held ionization chamber).

Electron Microscopes

A radiation survey for x-ray leakage should be performed at the time of installation; any time the microscope is moved, modified, or attachments/accessories are added/removed; when any part of the metal casing or viewing windows are removed; or if the current level is set higher than normal.

When surveying, the following parts of the microscope should be examined closely:

- Gun
- Camera/viewing chamber
- Specimen changer
- Junctions between column sections
- Attachment joints

If possible, radiation surveys should be carried out under “worst case” conditions, such as highest acceleration voltage, highest beam current, beam at crossover on specimen, low magnification, or all apertures removed.

A scintillation counter can be used to detect x-ray leakage. However, the energy dependent response of a scintillation counter makes it inappropriate for measuring x-ray leakage. When measurement of x-ray leakage is desired, an appropriately calibrated air ionization chamber should be used. It is recommended that the x-ray exposure rates do not exceed 0.5 milliroentgen per hour at 5 centimeters from the surface of the unit.

8.4.6 Surveys of Lasers

Surveys of lasers should be performed to confirm that:

- All lasers and protective devices are labeled correctly and functioning within design specifications
- All warning devices are functioning within their design specifications
- The laser installation is properly posted with warning signs

8.5 Protective Equipment and Clothing

Upgraded protective clothing and equipment may be required by the RSO or SHEMP Manager to shield or isolate an individual from radiological or chemical hazards that may be temporarily encountered in cases of major accidents or spills. Protection levels and equipment required for specific conditions are described in "Field Standard Operating Procedure (FSOP) Number 4—Site Entry" and "Field Standard Operating Procedure (FSOP) Number 6—Work Zones."

All protective clothing and equipment, as well as proper training for its use, will be provided by the laboratory SHEMP Manager or RSO. Storage and maintenance of protective clothing and equipment is the responsibility of the worker to which it is assigned. More information on personal protective clothing and equipment can be found in Chapter E.

8.5.1 Nonionizing Radiation

Where engineering controls do not sufficiently reduce or eliminate exposure hazards, staff working with or near nonionizing radiation should be adequately protected against hazards through the use of protective equipment and clothing.

8.5.2 Lasers

Protective equipment for laser safety generally means eye protection in the form of goggles or spectacles, clothing, and barriers and other devices designed for laser protection.

Eye Protection Devices

Engineering controls, which are built into laser equipment by the manufacturer, are the primary means of controlling laser hazards. Examples of these include protective housing, fail-safe interlocks, master switch controls, and beam stops or attenuators. However, OSHA requires eyewear in addition to engineering controls whenever accessible emission levels exceed maximum permissible exposure levels.

Eyewear should be selected for good visibility and comfort. However, there are many factors that must be taken into account when selecting protective eyewear for use with lasers. These are summarized in Attachment C6-6.

Skin protection can best be achieved through engineering controls. If the potential exists for damaging skin exposure, particularly for ultraviolet lasers (0.200-0.400 m), then skin covers and/or sunscreen creams are recommended. For the hands, gloves will provide some protection against laser radiation. Tightly-woven fabrics and opaque gloves provide the best protection. A laboratory jacket or coat can provide protection for the arms. For Class IV lasers, flame-resistant materials may be best.

Laser Barriers and Protective Curtains
Area control can be effected in some cases using special barriers specifically designed to withstand either direct or diffusely scattered beams. The barrier will be described with a barrier threshold limit (BTL); the beam will penetrate the barrier only after some specified exposure time, typically 60 seconds. The barrier is located at a distance from the laser source so that the BTL is not exceeded in the worst-case exposure scenario.

Currently available laser barriers exhibit BTLs ranging from 10 to 350 W/cm^2 for different laser wavelengths and power levels. An analysis conducted in a manner similar to the NHZ evaluations described previously can establish the recommended barrier type and installation distances for a given laser.

It is essential that the barrier not support combustion or be itself consumed by flames during or following a laser exposure.

In general, other controls should serve as primary protection rather than depending on employees to use protective eyewear. Many accidents have occurred when eyewear was available but not worn. This may be because laser-protective eyewear is often dark and uncomfortable to wear, and limits vision.

8.5.3 RGDs

During the operation of RGDs, there should be no instance where staff exposure to radiation occurs. Normal operations of this equipment does not require the use of personal protective equipment or clothing to protect against radiation hazards.

Attachment C6-1: Laser Evaluation Checklist

Purpose: To provide a sample form to use when evaluating a laser installation.

Instructions: Use this form when evaluating a laser installation to determine if relevant requirements and safety measures are in place.

Laser Evaluation Checklist

Laser Emissions Description:
Type:

Classification Designation:

Class I	_____	Class IIIA	_____
Class IIA	_____	Class IIIB	_____
Class I	_____	Class IV	_____

Performance Requirements	Present	
	Yes	**No**
Protective housing—all classes—1940.10(f)(1)		
Safety interlocks—all classes—1940.10(f)(2) *Note: Requirements depend on class of internal radiation*		
Nondefeatable interlocks		
Defeatable interlocks		
Remote interlock connector—classes IIIB and IV—1940.10(f)(3)		
Key control—classes IIIB and IV—1040.10(f)(5)		
Emission indicator—classes II, III and IV—1040.10(f)(3) class II and IIIA: no delay—1040.10(f)(5)(I) class IIIB and IV: with delay—1040.10(f)(5)(I) indicators on laser and controls, if separated by more than 2 meters *Note: class IIA is exempt*		
Beam attenuator—classes IIA, III and IV—1040.10(f)(7)		
Location of controls—classes IIA, II, III and IV—1940.10(f)(7)		
Viewing optics—all classes—1940.10(f)(7)		
Scanning safeguard—all classes—1940.10(f)(9)		
Manual reset mechanism—class IV—1940.10(f)(10)		
Certification label—all classes—1010.2		
Identification label—all classes—1010.3		
Class designation and warning label—all classes except class I—1040.10(g)(1, 2 and 3)		
Radiation output information (position 2 on label)—classes II, III and IV—1040.10(g)(4) *Note: class IIA is exempt*		
Aperture label—classes II, III and IV—1040.10(g)(5) *Note: class IIA is exempt*		
Noninterlocked protective housing labels (i.e., service panels)—All classes—1040.10(g)(6)		
Defeatably interlocked protective housing labels—1040.10(g)(7)		
Warning for invisible radiation (whenever applicable—all labels)—1040.10(g)(8)		
Positioning of labels—1040.10(g)(9)		
Label specifications—1040.10(g)(10)		

Laser Evaluation Checklist

Information Requirements:	Present	
	Yes	No
User information—1040.10(h)(1)		
Operator and maintenance instructions—(h)(1)(I)		
Statement of parameters—(h)(1)(I)		
Label reproductions—(h)(1)(ii)		
Listings of controls, adjustments, and procedures, including warnings—(h)(1)(iv)		
Service information—1040.10(h)(2)(ii)		

Attachment C6-2: Classification of Lasers

Class	Description	Example	Safety Precautions
I	Exempt lasers or laser systems that cannot produce a hazard under normal operating conditions	Laser printer	None.
II	Low-power visible lasers or laser systems	Laser pointer	Do not permit a person to continuously stare in the laser source. Do not point the laser into a staff member's eye.
IIIa	Lasers or laser systems that normally would not produce a hazard if viewed for only momentary periods with the unaided eye (They may present a hazard if viewed using collecting optics such as a telescope or binoculars.)	Visible cw HeNe lasers above 1 mW but not exceeding 5 mW radiant power	Do not aim the laser at a staff member's eye. Permit only properly trained staff to operate the laser. Enclose as much of the beam path as possible. Beam stops should be used at the end of useful beam paths.
IIIb	Lasers or laser systems that can produce a hazard if viewed directly (This includes intrabeam viewing or specular reflections. Except for the higher power class IIIb lasers, this class laser will not produce hazardous diffuse reflections.)	Visible cw HeNe lasers above 5 mW but not exceeding 500 mW radiant power	Control spectators. Operate laser in restricted area only. Place the laser beam path well above or below the eye level of standing or sitting observers whenever possible. Always use proper eye protection if a potential eye hazard exists for the direct beam or specular reflections. Do not view the beam or its specular reflection with collecting optics. Removal all unnecessary mirror-like surfaces from within the vicinity of the laser beam path.
IV	Lasers or laser systems that can produce hazard not only from direct or specular reflections but also from a diffuse reflection (Such lasers may also produce fire hazards and skin hazards.)	cw lasers having accessible power greater than 500 mW	Operate within a strictly controlled area only. Wear proper eye protection within the controlled area. Use suitable shielding between the laser beam and any staff if beam irradiance is sufficient to be a serious skin or fire hazard. Use remote firing with video monitoring (or other safe remote viewing techniques) when feasible. Use beam stops constructed from fire-resistant material, or constructed so that the beam is diffusely reflected.

Attachment C6-3: Classification of Radiation-Generating Devices

Class	Exposure Potential	Design Features	Examples
I	***Incapable*** of reasonably producing an accidental dose >100 mrem/yr to either a localized area of the body (e.g., an eye or a finger) or to the whole body The dose should not be capable of reasonably exposing a person to localized or whole-body doses >100 mrem/yr.	Designed to be ***inherently safe***. Do not require significant occupancy controls or personnel in attendance.	Electron microscopes Cabinet x-ray systems certified in accordance with 21 CFR 1020.40 [ANSI's "Exempt Shielded Installations" category]
II	***Capable*** of reasonably producing accidental whole-body doses between 0.1 and 15 rem, extremity doses between 0.1 and 150 rem, or eye doses between 0.1 and 45 rem. ***Capable*** of reasonably producing up to three times the occupational annual dose limit to the whole body, extremities, or eyes, but are not likely to produce severe biological effects.	The ***primary beam*** may be inaccessible without disassembling the unit, enclosed during normal operations, or in an open-beam configuration. A ***secondary beam*** may be generated by diffraction or fluorescence and may be inaccessible, enclosed, or in an open-beam configuration. ***Interlocks*** are installed on these devices to prevent access during normal operation.	Low-intensity flash x-ray devices Radiographic x-ray devices Diffraction or fluorescence devices [ANSI's "Shielded Installations" category]
III	***Capable*** of reasonably producing an accidental extremity dose >150 rem or an eye dose >45 rem. ***Capable*** of reasonably producing more than three times the occupational annual dose limit to the extremities or the eyes, and may be capable of producing severe biological effects to localized areas of the body. These devices are unlikely to produce lethal doses of radiation due to the limited area of exposure.	The ***primary beam*** may be inaccessible without disassembling the unit, enclosed during normal operations, or in an open-beam configuration. A ***secondary beam*** may be generated by diffraction or fluorescence and may be inaccessible, enclosed, or in an open-beam configuration. ***Interlocks*** are installed to prevent access during normal operation.	Low-intensity flash x-ray devices Radiographic x-ray devices Diffraction or fluorescence devices [ANSI's "Shielded Installations" category]
IV	***Capable*** of reasonably producing an accidental whole-body dose >15 rem. ***Capable*** of reasonably producing more than three times the occupational annual dose limit to the whole body, and may be capable of producing lethal levels of radiation.	***Radiation shielding*** should be designed to limit personnel doses to less than one-tenth the maximum annual permissible dose (i.e., <500 mrem/yr).	Radiographic devices Particle accelerators

Attachment C6-4: Acceptable Package Limits

Radionuclide	Acceptable Quantity
Any byproduct material with Atomic Number 3 through 83, inclusive	1 mCi
Actinium-227	1 mCi
Americium-241	1 mCi
Americium-243	1 μCi
Californium-252	0.1 μCi
Cobalt-60	1 mCi
Curium-242	1 mCi
Curium-244	1 mCi
Curium-248	1 mCi
Krypton-85	1 mCi
Neptunium-237	0.5 μCi
Plutonium-236	1 μCi
Plutonium-238	1 μCi
Plutonium-239	1 μCi
Plutonium-242	1 μCi
Polonium-210	1 mCi
Protactinium-231	1 mCi
Radium-226	1 nCi
Thorium-229	1 μCi
Thorium-232	10 mCi
Uranium-232	1 mCi
Uranium-238	10 mCi
Uranium-235	10 nCi

Attachment C6-5: Selection of Laser Protective Eyewear

Factor	Discussion
Type of Laser	Eyewear depends on the wavelength and power density of the laser in use. For example, eyewear that protects against the carbon dioxide beam may not protect against the Ng:YAG laser.
Type of Eyewear	Goggles are recommended to protect against back reflection or side entrance of a stray beam. Lightweight laser protective spectacles, when properly fitted with side shields of the same material as the lenses, provide a good alternative to goggles.
Plastic vs. Glass	Protective lenses can be made of either plastic or glass. Glass is more easily scratched and does not resist impact as well as plastic. Plastic has a high heat-deflection temperature that enables lenses to withstand laser beams with high energy densities. It is also lightweight and capable of being molded into comfortable shapes. Plastic eyewear should be adequate for staff standing at a distance from the laser but not for technicians servicing the laser.
Reflective vs. Absorbtive Lenses	Protective lenses, both plastic and glass, are of two types: reflective or absorbtive. Reflective lenses have a thin surface coating that selectively reflects a given wavelength of the laser beam while transmitting the remaining visible spectrum. These lenses have good visibility; however, a surface scratch can allow penetration of the laser beam. In addition, the reflected laser beam remains a safety hazard to others nearby and there is a danger of fire if the beam hits a combustible or flammable item. Absorbtive filters on lenses converts the laser energy to heat, which is diffused through the lenses. They are not affected by surface scratches, and are less likely to cause hazardous beam reflections. However, they do not provide adequate impact resistance and the organic dyes used as absorbers are affected by heat and/or ultraviolet radiation.
Optical Density	The filtering ability of laser eyewear is rated by this factor and determined by the laser manufacturer. A high optical density at a given wavelength indicates greater laser beam absorbency. However, eyewear that is this efficient at protecting the wearer from the laser beam also causes reduced visibility. Eyewear should have the best visibility at the safest optical density. The optical density and wavelength the eyewear is designed for must be imprinted on the lens or frame.

1.0 Introduction

EPA laboratories working with micro-organisms, recombinant DNA (rDNA) technologies, laboratory animals, or bloodborne pathogens are special, and often unique, work environments. The materials being used may pose special risks to persons working in or near the laboratory if the material should escape the containment procedures established for the laboratory. It is the responsibility of the Biosafety Officer (BSO) or Safety, Health, and Environmental Management Program (SHEMP) Manager to work with researchers and technical staff to reduce the potential for personnel exposure or environmental release.

An effective biosafety program involves the control of a variety of biohazards to which laboratory employees may be exposed. These hazards include the following:

- Biological agents used in *in vitro* testing laboratory research
- Infectious agents carried by laboratory animals, particularly rodents and primates
- The potential of infection caused by exposure to blood or other potentially infectious material (OPIM) that may contain bloodborne pathogens (BBP)

This chapter provides guidance for EPA laboratories on the design and implementation of a biosafety program to control these hazards.

EPA Program Requirements

Each EPA laboratory must conduct an assessment to identify employees with biohazard exposure potential, as well as procedures that pose an exposure risk. For employees and identified procedures, laboratories must:

- Develop a biological safety plan.
- Train each employee included under the plan.
- Apply appropriate controls, including engineering, protective equipment, work procedures, and housekeeping techniques.
- Ensure that biohazardous materials are properly labeled, and that employees are familiar with the labeling system.
- Develop and implement decontamination procedures.
- Ensure that requirements of the U.S. Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens Standard in 29 CFR 1910.1030 are met if exposures involve blood or OPIM.

Program Administration

To effectively manage the laboratory biosafety program, responsibilities should be assigned for:

- Identifying employees with exposure potential and procedures posing an exposure risk
- Training employees in the elements of the biological safety plan

- Selecting and implementing appropriate exposure controls
- Evaluating the effectiveness of control techniques
- Ensuring the integrity of containment and decontamination procedures
- Maintaining required records

2.0 Overview of Guidelines and Standards

The Centers for Disease Control/National Institutes of Health (CDC/NIH) have published guidelines that apply to laboratories involved in work with infectious microorganisms and rDNA. In addition, guidelines for laboratory animal research (LAR) have been developed by the National Research Council (NRC). OSHA has promulgated the BBP Standard to protect workers who may be exposed to blood and OPIM. These guidelines and standards are outlined in the sections that follow and summarized in Figure C7-1.

2.1 CDC/NIH

The guidelines published by the CDC/NIH were developed to reduce employee exposure to potentially hazardous agents, and to prevent escape of these agents into the atmosphere. The guidelines describe four biosafety levels, or levels of containment, that consist of combinations of:

- Standard and special microbiological practices
- Safety equipment
- Facility design criteria appropriate for operations and infectious agents

Section 7.0 of this chapter addresses these guidelines in more detail.

2.2 NIH Guidelines for rDNA

Recombinant DNA molecules are defined as:

- DNA molecules that result from the replication of those molecules
- Molecules constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell

All laboratories working with rDNA must comply with applicable federal, state, and local guidelines and regulations. The federal guidelines are outlined by NIH, in the publication entitled *"Guidelines for Research Involving Recombinant DNA Molecules."*

2.3 NRC Animal Research Laboratory

The NRC has published the *Guide for the Care and Use of Laboratory Animals*. This guide assists laboratories in caring for and using animals in ways judged to be scientifically, technically, and humanely appropriate.

2.4 OSHA Standards

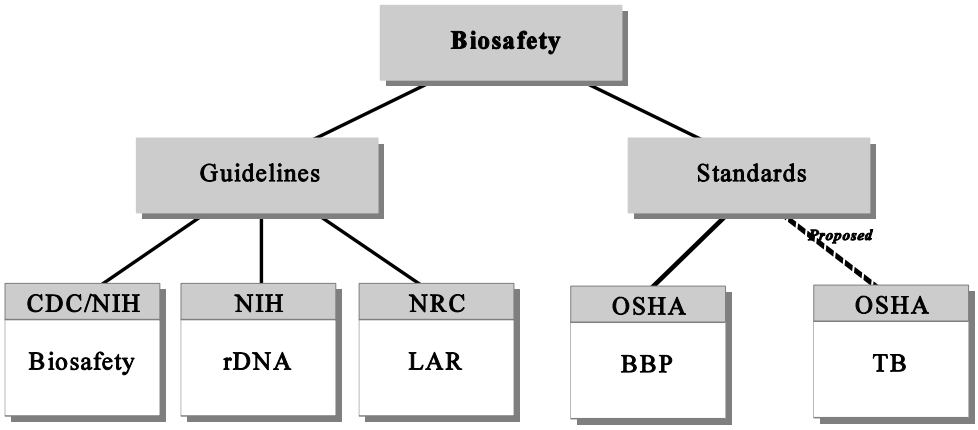
OSHA has increased efforts to protect workers who may be exposed to blood and OPIM that may harbor BBP and tuberculosis (TB) in the workplace. The following sections discuss the OSHA BBP Standard and proposed TB Standard.

2.4.1 BBP

The BBP Standard in 29 CFR 1910.1030 applies to any workplace where employees have reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or OPIM (e.g., human body fluids), regardless of the frequency of exposure.

> *Potentially infectious materials* refers to those materials that may carry organisms capable of causing disease in humans.

Figure C7-1: Biosafety Guidelines and Standards



The standard contains various requirements for a BBP management program, including the development of an exposure control plan. Section 9.0 of this chapter discusses the specific requirements of the BBP standard in more detail.

2.4.2 TB

On October 17, 1997, OSHA published the proposed standard on occupational exposure to TB. EPA laboratories may be subject to this standard if any handling or analysis of TB-contaminated specimens is performed. Under the proposed standard, employers of a covered facility would be required to:

- Develop and implement a written exposure control and response plan
- Offer all employees a free TB skin test at a time and place convenient to the employee, with the test results read and analyzed by a trained professional
- Train employees in recognizing the signs and symptoms of infection, modes of transmission, prevention, identifying tasks or areas that might increase exposure risk, isolation procedures for suspected cases, and the link between HIV infection and TB
- Control exposure to staff where there are high-risk groups with stays of long duration

2.5 Local Regulations

In addition to the NIH guidelines governing research with rDNA, local regulations exist to ensure their proper use. Local ordinances outline permit requirements, restrictions, and penalties associated with research involving rDNA.

3.0 Biosafety Responsibilities

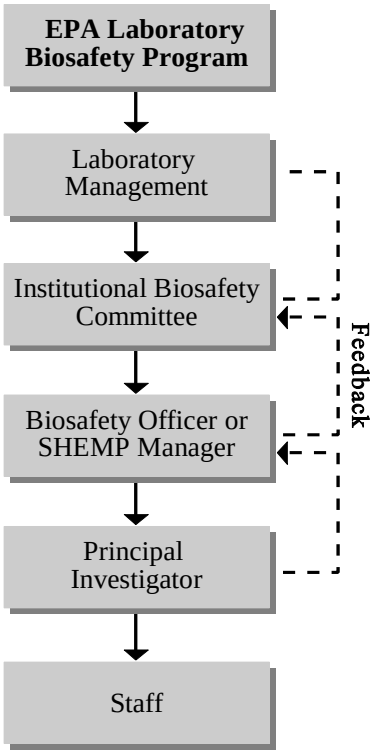
The biosafety program organization is shown in Figure C7-2. Responsibilities for each of these positions are discussed in the following sections.

3.1 Principal Investigators

Developing and maintaining a healthful and safe work environment depends on the day-to-day supervision of research by personnel with a positive safety attitude. The principal investigator (PI) is responsible for complying fully with federal, state, and local regulations and/or standards. The PI must:

- Determine the known or potential biohazards associated with the proposed experiments.
- Submit a biohazardous research checklist to the BSO or SHEMP Manager.
- Provide supervised personnel with knowledge of biohazards to which they may be exposed and safety procedures to be followed.
- Report (in writing) to the BSO any accident, personnel exposure, suspected illness, escape of biohazardous agents, and significant problems pertaining to the operation and implementation of containment practices and procedures.
- Arrange for physical examinations and other medical surveillance of personnel when required by the nature of the experiments.
- Ensure the integrity of the physical containment (e.g., biological safety cabinets) and biological containment.

Figure C7-2: Biosafety Program Organization



- Maintain knowledge of, and adhere to, the permit requirements of federal and state agencies for interstate and international movement of biohazardous agents.

3.2 Biosafety Committee

The institutional biosafety committee (IBC) serves to advise the laboratory's management on policies pertaining to biohazardous research. The committee recommends standards under which biohazardous activities should be conducted, and reviews projects for compliance with appropriate federal guidelines and regulations. Other specific responsibilities include:

- Reviewing the appropriateness and adequacy of containment levels and safety measures proposed and/or used in research

- Assessing the adequacy of containment facilities for biosafety level 3 (BL3) agents and rDNA molecules, as required by NIH or regulatory agencies

- Developing informational and training seminars and workshops on biohazards

- Periodically reviewing current biohazardous research to ensure that requirements are being fulfilled

- Recommending appropriate sanctions for noncompliance with biosafety standards, guidelines, or regulations

- Adopting emergency plans covering accidental spills and personnel contamination resulting from biohazardous research

The minimum composition of the IBC, as specified by NIH, includes:

- Five members with expertise and experience in SHE issues related to rDNA technology

- Two members who are not affiliated with public health or the environment

- Two members who are not otherwise affiliated with the laboratory

In addition, when experiments using animals or plants require prior IBC approval, there must be at least one scientist with expertise in plants or pathogens or plant pest containment and one scientist with animal containment expertise on the IBC.

3.3 BSO or SHEMP Manager

The EPA laboratory's BSO or SHEMP Manager has responsibility for the daily administration of standards set by the IBC and acts on behalf of the committee in their implementation. Other responsibilities may include:

- Performing preliminary screening of biohazardous research checklists and assigning them to the IBC for review

- Arranging for initial and periodic inspections of laboratories used in biohazardous research

- Providing technical advice to PIs and to the IBC on research safety procedures

- Organizing and conducting training on biohazards

- Arranging for appropriate medical surveillance of personnel working with certain biohazardous agents

- Providing technical advice regarding biohazard safety needs and requirements for projects involving the renovation or construction of laboratory or other facilities where biohazardous agents will be used

3.4 EPA Laboratory

The EPA laboratory and its managers are ultimately responsible for the following:

- Developing and maintaining appropriate policies regarding biohazardous research
- Developing mechanisms for ensuring adherence to biosafety policies
- Providing the resources necessary to implement the biosafety program

4.0 Types of Biohazards

Biohazards found in EPA laboratories can be in the form of biohazardous agents, animals, and plants as shown in Figure C7-3.

4.1 Biohazardous Agents

A biohazardous agent is biological in nature, is capable of self-replicating, and can cause disease in susceptible organisms, particularly humans.

Biohazardous agents can be found in a variety of environments, such as laboratories and indoor air, and can be harbored in a number of different media, including:

- Experimental tissues and cells
- Human blood and OPIM
- Laboratory animals
- Human and animal wastes

This section describes two types of biohazardous agents: infectious and rDNA.

4.1.1 Infectious Agents

Infectious agents generally fall into one of six types: viral, bacterial, parasitic, fungal, rickettsial, and protozoan. Each are described in the following sections, and Table C7-1 presents examples of diseases caused by each type.

Viral Agents

Viruses are pathogens that depend on other organisms to survive and reproduce. There are many different types and strains that can cause a wide range of diseases. Since few medications are effective in treating viral infections, the body's immune system serves as the primary mechanism for eliminating these pathogens. To fight a viral infection, the body's white blood cells produce antibodies that attack the specific

Figure C7-3: Biohazards at EPA Laboratories

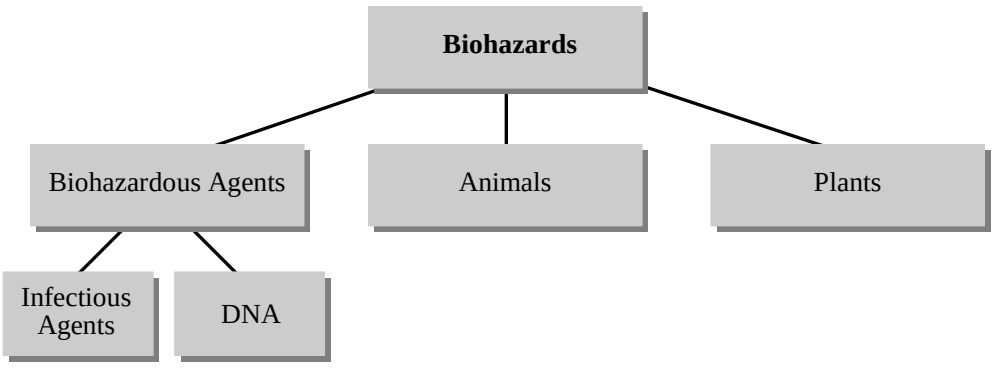
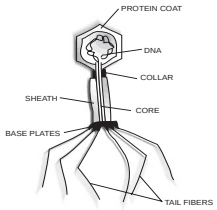
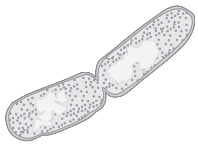
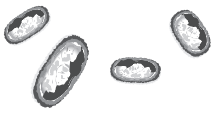
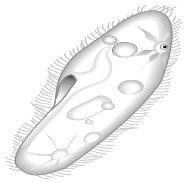


Table C7-1: Types of Infectious Agents

Agent Type	Diseases
Viral 	• Hepatitis A and B • Herpes • HIV Infection • Influenza • Lymphocytic choriomeningitis • Poliomyelitis • Rabies
Bacterial 	• Tuberculosis • Bacterial Meningitis • Typhoid • Cholera • Shigellosis • Strep Throat (Streptococcus) • Food Poisoning
Parasitic 	• Hookworms • Tapeworms • Giardia
Fungal 	• Dermatomycosis • Ringworm • Blastomycosis • Coccidioidomycosis
Rickettsial 	• Rocky mountain spotted fever • Typhus • Q Fever
Protozoan 	• Malaria • Amoebic dysentery

pathogen and weaken and destroy it. However, some viral pathogens can overtake the body's immune system and result in death.

BBP refers to pathogenic microorganisms that are present in human blood and in OPIM and can cause disease in humans, including:

- Hepatitis B (HBV), the causative agent of Hepatitis—a serious liver disease
- Human immunodeficiency virus (HIV), the causative agent of acquired immunodeficiency syndrome (AIDS)

OPIM may include:

- Semen
- Vaginal secretions
- Cerebrospinal fluid
- Synovial fluid
- Pleural fluid
- Pericardial fluid
- Peritoneal fluid
- Amniotic fluid
- Saliva
- Any body fluid that is visibly contaminated with blood
- Unfixed human tissue or organ (other than intact skin)
- HIV-containing cell, tissue, or organ cultures
- HIV/HBV-containing culture media or other solutions

Bacterial Agents

Bacteria are present everywhere and, unlike viruses, do not depend on other organisms for life. Although most bacteria do not infect humans, those that do can cause serious illness. Bacterial infections are difficult to fight with the body's own immune system, and often must be treated with prescription medication, such as antibiotics (e.g., penicillin, erythromycin).

Parasitic Agents

Parasites, such as hookworms, rely on the host to survive and reproduce. Symptoms of a parasitic infection may include abdominal pain, diarrhea, anemia, and respiratory and circulatory complications.

Fungal Agents

Fungi, which include yeasts, molds, and mushrooms, can cause numerous diseases in humans, usually by skin contact or by inhalation of spores.

Rickettsial Agents

Rickettsia are a type of bacteria that occur as parasites in lice, fleas, ticks, and mites. These organisms can be transmitted to humans and animals.

Protozoan Agents

Protozoa are single-celled organisms that are mostly free-living. They can be transmitted to humans through infected animals and insects (e.g., mosquitoes), or through ingestion.

4.1.2 Recombinant DNA

Laboratory-acquired seroconversions (i.e., antibody production) from rDNA-derived proteins or sensitization to crude or purified microbial proteins (or glycoproteins) have been reported. Therefore, rDNA require special handling precautions to address these risks.

4.2 Vertebrate Animals

Laboratory animal research (LAR), and ongoing care of animals, carries some inherent risks for injury to the staff involved, including employee injury (e.g., bites and scratches) and the transmission of disease preventing cross-infection is of prime importance.

Animals, particularly nonhuman primates (NHPs), have the potential to carry and transmit diseases that can be pathogenic to humans. Those diseases that are of particular concern to laboratory employees (e.g., *Herpes simiae*, tetanus, bacterial infections, Hepatitis and tuberculosis) are described in the following sections.

4.2.1 Herpes Simiae

The *Herpes simiae* virus is one of the more pathogenic viruses to humans; however, the overall risk of transmission appears to be low. Macaque monkeys are natural hosts to the *Herpes simiae* (i.e., Herpes B) virus, and can be infected without initially showing any symptoms. NHPs infected with this virus eventually suffer only a mild clinical disease similar to Herpes simplex in humans; however, humans, if infected, suffer catastrophic consequences.

During periods of viral shedding, transmission to humans can occur by several means. Exposure to infected saliva by bites or scratches, or injuries where equipment contaminated with body fluids break the skin or mucosa, are considered to carry risk of infection. Deep penetrating wounds, such as cuts from cages or scalpels and punctures with needles, carry the greatest risk. Aerosol transmission may be possible, but the risk is low. Although clinical infection in humans is uncommon, once it develops, infection nearly always results in severe or fatal disease. Clinical signs that may occur two to 54 days following exposure are shown in Table C7-2.

4.2.2 Tetanus

Tetanus is caused by a toxin produced by *Clostridium tetanii* (e.g., tetanus bacillus), and can be found in the intestines of animals, or in soil or dirt that has been contaminated with animal or human feces.

The tetanus bacillus can be introduced to humans at the site of a contaminated injury such as a cut or an animal bite. If the wound closes over the bacillus and no air can enter the site, the bacillus then grows anaerobically (i.e., without oxygen). Deep wounds that are difficult to clean carry the greatest risk.

The bacteria invade the nervous system, causing progressive muscle spasms. Case fatality rates range from 30 to 90 percent. However, tetanus vaccines have been proven effective in preventing the disease.

4.2.3 Bacterial Infections

A large number of bacterial species reside in the mouths of NHPs and other animals and can be transmitted to humans through bites. Some of these bacteria are pathogenic, others are not. For example, *Eikinella corrodens* is quite virulent and can cause severe cellulitis (i.e., skin infection). Streptococcal bacteria are also among some of the potential pathogens.

Table C7-2: Clinical Signs of Herpes Simiae Infection in Humans

Manifestations	Signs of Infection
Early	• Vesicular eruptions or ulcerations at or near the exposure site • Severe pain or itching at the exposure site
Intermediate	• Fever • Numbness and/or tingling at or near the exposure site that progresses toward the torso • Muscle weakness or paralysis in the exposed extremity
Late	• Paralysis or numbness and tingling on either side of the body • Neck stiffness • Headache lasting more than 24 hours • Nausea and vomiting • Altered mental state • Other signs of central nervous system impairment

Thorough wound cleaning is essential to preventing bacterial infections following a bite or scratch, as is evaluation by medical personnel for additional cleaning and treatment with antibiotics.

4.2.4 Hepatitis

Hepatitis A and E are both enteric (i.e., located in the intestines), and can be carried by monkeys. Since these viruses are transmitted by ingestion of fecal-contaminated water or food, they are not a significant risk to laboratory personnel if proper work practices are followed.

Hepatitis B, C, and D are bloodborne viruses and are not carried by monkeys; however, monkeys can be a susceptible host. Therefore a blood-to-blood exposure involving a sick monkey could pose a risk (e.g., needlestick, laceration, or splash of monkey blood onto a caretaker's mucous membranes). Universal precautions and vaccination can prevent infections.

4.2.5 Tuberculosis

Tuberculosis is caused by the Mycobacterium *tuberculosis bacillus* which can cause disability or fatal disease, usually of the respiratory system. This bacteria is generally not found in monkeys, but can be transmitted to the monkeys from humans and then spread among the other animal population.

4.3 Plants

Plants used in laboratory research may contain biohazardous agents such as rDNA. Their release into the environment is prevented using biosafety containment measures for plants.

5.0 Routes of Infection

Pathogens must have access into the body through a specific route of exposure for biohazardous agents to be transmitted. Some of the most common routes include skin contact, ingestion, inhalation, and injection. Some biohazardous agents can

enter the body by any one of these routes, while others can only be transmitted by one or two modes of entry. In addition, vector transmission is a route of exposure that can occur when handling laboratory animals. The following sections briefly describe each of the more common routes of entry for biohazardous agents. Figure C7-4 presents a summary of these routes of entry.

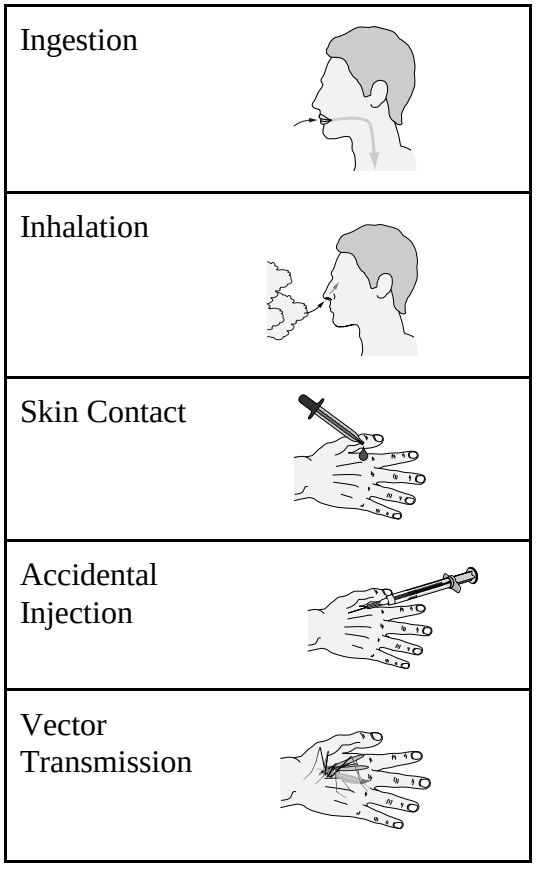
5.1 Skin Contact

Skin is an excellent barrier. However, depending on the pathogen, biohazardous agents can be transmitted through intact and non-intact skin, as well as through the mucous membranes of the eyes, nose, or mouth.

Some pathogens, including many parasites, can penetrate intact skin to cause disease, while others, such as HIV and Hepatitis, can be transmitted only from blood-to-blood contact with infectious body fluids (e.g., semen). However, these infectious pathogens can enter the bloodstream through breaks in the skin such as open wounds, scratches, insect bites, rashes, burns, and shaving nicks.

In addition to direct contact, biohazardous agents can be indirectly transmitted through the skin or mucous membranes. For example, handling contaminated objects or equipment and then rubbing eyes, nose, or skin creates an entry route for biohazardous agents.

Figure C7-4: Routes of Infection



5.2 Ingestion

Accidental ingestion of a biohazardous agent can occur from the following:

- Ingestion of contaminated food and water
- Indirect transfer of the agent from hand to mouth by contaminated fingers or gloves
- Mouth pipetting

Examples of biohazardous agents that are often transmitted from accidental ingestion include parasites (e.g., tapeworms and giardia), Hepatitis A, and agents causing food poisoning (i.e., bacterial infection).

5.3 Inhalation

Airborne transmission of a biohazardous agent takes place when the pathogen is inhaled. In a laboratory, aerosols can be produced by a number of operations and practices involving biohazardous materials. For example:

- Animal inoculation
- Centrifugation
- Blending, vigorous shaking, or mixing
- Sonic disruption
- Opening containers of infectious materials
- Harvesting infectious tissues from animals or eggs
- Handling or shaking contaminated animal cage litter and bedding

Microorganisms can proliferate in the water used for humidification or cooling and be distributed by the air heating, ventilation and air conditioning system (HVAC) system.

Examples of diseases that are caused by the inhalation of biohazardous agents include tuberculosis, bacterial meningitis, coccidioidomycosis, and influenza.

5.4 Accidental Injection

Accidental injection of a pathogen into the bloodstream is a significant route of exposure, especially for laboratory workers handling hypodermic needles, syringes, and intravenous (IV) sets. Personnel may also be at risk of infection from broken glass, needles, or other sharp objects when handling wastes or responding to accidents or emergencies.

Biohazardous agents that can be transmitted from accidental injection include HIV, Hepatitis, and tetanus.

5.5 Vector Transmission

Vector transmission can occur when an infected human, animal (e.g., dog or raccoon), or insect (e.g., tick or mosquito) transmits the pathogen into the body through a bite. Rabies, tetanus, and Lyme disease are examples of vector-transmitted conditions.

The risk of vector-borne transmission is low for most EPA laboratory staff. However, personnel should be aware of this hazard when working in laboratories where animals are handled, and during emergency situations.

6.0 Risk Assessment

The classification and evaluation of organisms should be based on a thorough risk assessment of the agent and activity. This risk assessment and subsequent selection of the appropriate hazard class and biosafety level must take into account several factors, including:

- Virulence of the organism
- Pathogenicity of the organism
- Stability of the organism
- Communicability of the organism
- Function of the laboratory and the procedures to be used
- Quantity and concentration of agent used
- Availability of effective vaccines

For example, when examining the classification of HBV it is important to know that it is:

- Among the most ubiquitous of human pathogens
- The most prevalent of laboratory-associated infections
- Identified in a variety of body secretions and excretions, including blood and saliva

However, it is of equal importance that the primary risk of HBV infection is only through accidental inoculation, exposure to broken skin or the mucous membranes, or ingestion of infectious body fluids. Since these risks are adequately controlled by biosafety level two (BL2) containment practices (see section 7.0 of this chapter for information on containment levels), HBV could be considered a Class 2 microorganism under certain conditions of use.

The CDC/NIH guidelines contain agent summary statements that provide agent-specific hazard information that should be used in selecting biosafety levels. A comprehensive list of the suitable organisms for each of the biosafety levels is presented in Attachment C7-1.

7.0 Biosafety Containment

The basic strategy behind biosafety is containment, which is the use of safe methods to reduce exposure to potentially hazardous agents, and to prevent the escape of biohazardous agents into the atmosphere.

Primary containment protects personnel and the inside environment from exposure, and is achieved by both adhering to safe work practices and good microbiological techniques and by using appropriate safety equipment.

Secondary containment protects the outside environment from exposure to infectious agents, and is accomplished through the design of the laboratory itself and the proper management of operations.

The elements of containment and biosafety are discussed below.

7.1 Biosafety Levels of Containment for Biohazardous Agents

Biosafety levels describe the degree of containment (or the combinations of standard and special practices, safety equipment, and facility design criteria) appropriate for the operations performed and the biohazardous agents used within the laboratory. Each biosafety level is discussed as follows, with a summary of recommended practices and techniques presented in Table C7-3. In addition, Attachment C7-2 presents a very detailed discussion of these practices.

Biosafety Level 1 (BL1)
BL1 is suitable for work with microorganisms not known to cause disease in healthy adult humans. Work is generally performed on open benchtops. Special containment equipment and devices are not usually needed.

Biosafety Level 2 (BL2)
BL2 applies to work with microorganisms of moderate potential hazard to employees and the environment. These agents can usually cause disease in healthy individuals. For BL2 laboratories, access is usually limited and work may be conducted in biological safety cabinets (BSCs) if

aerosols may be produced. Additional information on BSCs, including maintenance, is included in Chapter D4 of this manual.

Biosafety Level 3 (BL3)
BL3 is used to work with indigenous or exotic agents where the potential for infection is real, and the disease may have serious or lethal consequences. Almost all work with these agents is conducted in BSCs and the laboratory may have specific design features, such as airlock entrance zones.

Biosafety Level 4 (BL4)
BL4 is required for work with agents that present a high individual risk of life-threatening disease. This is the highest level of containment and requires a containment facility designed to be completely isolated from all other buildings.

7.2 Biosafety Levels of Containment for Vertebrate Animals

When experimental animals are used, the CDC/NIH guidelines describe combinations of laboratory practices, safety equipment, and facilities for experiments with infected animals. Four combinations, designated animal biosafety levels (ABSL) 1 to 4, are comparable to the biosafety levels recommended for use with infectious agents. In general, the animal biosafety levels have added:

- Specifications for handling and decontaminating animal cages and bedding
- Special provisions for personal protective equipment
- Requirements that floor drains be filled with disinfectant or water
- Special design criteria for animal facilities

Table C7-3: Recommended Biosafety Practices and Techniques

Biosafety Level	Practices	Safety Equipment	Facility Design
BL1	Standard microbial practices	Standard laboratory practices; open bench	Basic
BL2	BL1 practices, plus: • Laboratory coats • Decontamination of waste • Limited access • Protective gloves • Warning signs	Partial containment (i.e., Class I or II BSCs)	Basic
BL3	BL2 practices, plus: • Special laboratory clothing • Controlled access	Partial containment equipment for all handling procedures	Containment
BL4	BL3 practices, plus: • Entrance through clothes-change room • Shower on exit • All wastes decontaminated	Maximum containment equipment (i.e., Class III BSC or partial containment equipment with full-body, air-supplied, positive-pressure suit) for all activities	Maximum containment

Table C7-4 presents a summary of recommended practices and techniques for working with animals and Attachment C7-3 of this chapter presents a detailed discussion of these practices.

7.3 Biosafety Containment for Plants

The principal purpose of plant containment is to avoid unintentional:

- Transmission of rDNA-containing plant genome, including nuclear or organelle hereditary material
- Release of rDNA-derived organisms associated with plants
- Release of nonindigenous species
- Release of plant pathogens or pests

The containment principles are based on the recognition that the organisms pose no health threat to humans or the other higher animals unless deliberately modified to do so. The intent of containment is to minimize the possibility of unanticipated deleterious effects on organisms and ecosystems outside the experimental facility.

Laboratory experiments with biohazardous plant materials are to be conducted at BL2.

8.0 Administrative Controls

Administrative controls in a biosafety program include:

- Biohazard communication
- Training
- Inspections
- Medical surveillance

Each of these are described in the following sections and shown in Figure C7-5.

8.1 Biohazard Communication

In addition to the primary and secondary containment practices used in biosafety laboratories, EPA laboratory personnel should be aware of, and be able to identify, the symbols and labels used for hazard communication. For biohazardous materials, labels include the universal biohazard symbol and hazard warning signs, including the biosafety level.

8.1.1 Labeling

Where biohazardous agents are used, stored or handled, most facilities will label equipment, storage containers, and rooms with the following label:

These labels are usually fluorescent orange or orange-red, with lettering or symbols in a contrasting color.

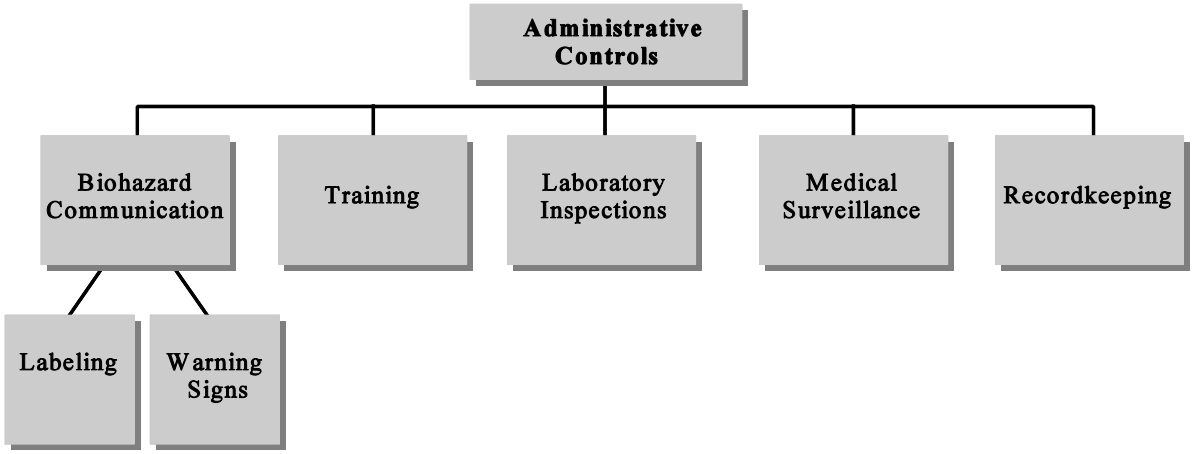
Labeling with the universal biohazard symbol is required for regulated waste, bags, and containers of contaminated laundry; refrigerators and freezers containing blood or OPIM; and other containers used to store, transport, or ship blood or OPIM.

In some cases, the use of red bags or containers may be substituted for labels.

Table C7-4: Biosafety Levels for Work with Vertebrate Animals

Animal Biosafety Level	Practices	Safety Equipment	Facilities
ABSL1	Standard animal care and management practices, including appropriate medical surveillance programs	As required for normal care of each species	• Standard animal facility • No recirculation of exhaust air • Directional air flow recommended
ABSL2	ABSL1 practices, plus: • Limited access • Biohazard warning signs • Sharps precautions • Biosafety manual • Decontamination of all infectious wastes and all animal cages prior to washing	ABSL1 equipment, plus: • Containment equipment appropriate for animal species • PPE: laboratory coat, gloves, and face and respiratory protection, as needed	ABSL1 facility, plus: • Autoclave • Handwashing sink in the animal room
ABSL3	ABSL2 practices, plus: • Controlled access • Decontamination of clothing before laundering • Cages decontaminated before bedding removed • Disinfectant foot bath as needed	ABSL2 equipment, plus: • Containment equipment for housing animals and dumping cages • Class I or II BSCs available for manipulative procedures (inoculation, necropsy) that may create infectious aerosols • PPE: appropriate respiratory protection	ABSL2 facility, plus: • Physical separation from access • Self-closing, double-door access • Sealed penetrations • Sealed windows • Autoclave available in facility
ABSL4	ABSL3 practices, plus: • Entrance through change room where personal clothing is removed and laboratory clothing is put on; shower on exiting; • Decontamination of all wastes before removal from the facility	ABSL3 equipment, plus: • Maximum containment equipment (i.e., Class II BSC or partial containment equipment in combination with full-body, air-supplied positive-pressure personnel suit) used for all procedures and activities	ABSL3 facility, plus: • Separate building or isolated zone • Dedicated supply/ exhaust, vacuum, and decontamination systems • Other requirements

Figure C7-5: Administrative Controls for a Biosafety Program



Labeling is not required for containers and bags that hold the following:

- Clinical specimens, if universal precautions are observed
- Decontaminated (e.g., autoclaved) regulated waste
- Blood or OPIM placed in secondary, labeled containers prior to storage, transport, or disposal
- Blood, blood products, or blood components that have been released for clinical use (e.g., transfusion) because they have been screened for HBV and HIV

8.1.2 Biohazard Warning Signs

In addition to labels, the entrance to a laboratory involved in the manipulation or storage of biohazardous materials, including blood and laboratory animals, is to be posted with a biohazard sign. This sign may include the universal biohazard symbol, the agent in use, the criteria for entry (e.g., vaccinations, personal protective equipment), and one of the four biosafety levels.

At the entrances to work areas in HBV/HIV research laboratories and production facilities, employers must post a sign containing the biohazard label, the name of the agent, special requirements for entering the area (e.g., personal protective equipment, vaccinations), and the name and telephone number of a contact person.

8.2 Training

All EPA laboratory employees must be adequately trained prior to beginning any work with biohazardous agents or NHPs. Requirements include training at the time of initial assignment and when changes in work tasks or operations create new exposure situations. Training must include instruction by a person knowledgeable in the subject matter as it relates to

the laboratory, and must include an opportunity for questions and answers between the trainer and employees. In addition, refresher training must be conducted annually. Refer to Chapter C3 of this manual for additional specific biosafety training guidance.

8.3 Laboratory Inspections

To ensure that the biosafety program continues to be effective and up-to-date, the program must be periodically reviewed. As part of this process, work practices and engineering controls should be routinely evaluated to ensure compliance with regulatory requirements and laboratory procedures, as well as to identify and correct any potential hazards. This evaluation can be accomplished through a walk-through of laboratory areas and a visual inspection of work practices.

The BSO should annually inspect each BL1 and BL2 laboratory areas to observe the physical containment practices in operation. Laboratory employees may be required to demonstrate knowledge of any appropriate laboratory practices during the inspection. Such inspections may also involve members of the IBC.

The results of all inspections will be reported to the appropriate personnel, including the members of the IBC, the SHEMP Manager, and the PI responsible for the laboratory.

8.4 Medical Surveillance Program

Recommendations for staff inclusion in a medical surveillance program should be made based on the hazards of the work and the individual needs of the workers. An exposure control plan for BBP should also have medical surveillance considerations for Hepatitis B vaccinations and post-exposure evaluation and follow-up.

For more information about medical surveillance requirements for biohazards, refer to Chapter C2 of this manual.

8.5 Recordkeeping

Records of exposure monitoring, incidents such as spills or releases, and waste disposal, should be retained at a minimum. Recordkeeping requirements under the BBP standard primarily pertain to medical- and training records. Refer to Chapter C2 of this manual for medical record retention requirements. Refer to Chapter C3 of this manual for BBP training recordkeeping requirements.

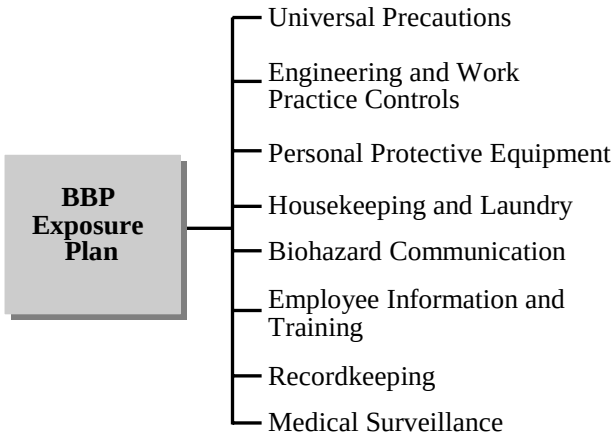
9.0 BBP Exposure Control Plan

SHEMP Managers of laboratories that handle blood or OPIM must:

- Identify all employees with exposure potential and all procedures that pose an exposure risk.
- Develop an exposure control plan that includes the measures to be taken to minimize the risk of exposure to BBP.

The exposure control plan must be designed to eliminate or minimize employee exposure to BBP. The plan must contain a schedule and methods of implementation for the elements of the standard as shown in Figure C7-6.

Figure C7-6: Components of a BBP Exposure Control Plan



The plan should provide guidelines and procedures addressing these elements. The following sections discuss the first four of these program elements. The remaining topics are covered elsewhere in this chapter as part of a biosafety program.

9.1 Universal Precautions

The phrase *universal precautions* means treating all blood and OPIM as potentially infectious materials in order to prevent contact. Under circumstances in which differentiation between body fluid types is difficult or impossible, all body fluids should be considered potentially infectious. Personnel should follow universal precautions and use appropriate personal protective equipment for all procedures involving blood and other body fluids.

9.2 BBP Engineering and Work Practice Controls

Engineering controls are used to either remove the pathogenic hazard, or to isolate the worker from the pathogen. These types of controls should be used in combination with safe work practices to provide the primary means of employee protection. Work practice controls are modified procedures and practices that will reduce the risk of worker exposure to BBP. Table C7-5 provides a summary of engineering and work practice controls. Chapter D of this manual provides more detailed information on engineering controls and Chapter F provides information on work practice controls.

9.3 BBP Personal Protective Equipment

If the exposure potential exists, after the implementation of engineering controls and work practice controls, then personal protective equipment (PPE) must also be used. Appropriate PPE does not permit blood or OPIM to pass through or reach the employees' skin, eyes, mouth, or other

Table C7-5: Engineering and Work Practice Controls

Engineering Controls	• Sharps containers for storing potentially contaminated needles and sharp objects • Mechanical needle recapping devices • Local exhaust ventilation, including biological safety cabinets • Secondary containment features
Work Practice Controls	• Use of adequate handwashing facilities • Proper handling and storage of contaminated sharps • Laboratory hygiene (i.e., no eating, drinking, smoking, etc.) in areas where there is potential of exposure to BBPs • Cleaning and disinfection of potentially contaminated work surfaces • Proper packaging of blood and OPIM for shipping and transport

mucous membranes under normal conditions. It should be worn when handling, transporting, decontaminating, or disposing of materials potentially contaminated with BBP. PPE typically includes:

- Disposable gloves
- Utility gloves for handling sharp objects
- Gowns or lab coats
- Face shields, masks, and eye protection
- Disposable resuscitation masks or microshields for use during artificial respiration

The CDC guidelines for laboratories make specific PPE recommendations based on the biosafety levels of the laboratory. The CDC also makes recommendations for PPE for workers in vertebrate animal research facilities.

These recommendations can be found in Attachments C7-2 and C7-3 on biosafety levels. For more information on the use and maintenance of PPE, refer to Chapter E of this manual.

9.4 Housekeeping and Laundry

Housekeeping procedures are an important part of limiting exposure to biohazardous material. The main function of housekeeping procedures is to prevent the accumulation of wastes that:

- Could shelter microorganisms that threaten the integrity of the systems under study
- May enhance the survival of microorganisms accidentally released in experimental procedures
- May retard penetration of disinfectants
- Could be transferred from one area to another on clothing and shoes
- Have the potential, with sufficient buildup, to become a biohazard due to aerosolization by personnel and air movement

- Could cause allergic sensitization of personnel

When performing housekeeping duties involving floor care, avoid dry sweeping and dusting to reduce aerosol formation. Wet mopping or vacuum cleaning with a high-efficiency particulate air (HEPA) filter is recommended.

When dry sweeping is the only method available, use push brooms and dry-dust mopheads treated to suppress aerosolization of dust.

10.0 Decontamination

The objective of decontamination is not only to protect personnel and the environment from exposure to biohazardous agents, but also to prevent contamination of experimental materials (e.g., stock cultures of viruses, bacteria, and cells) by viable, persistent, and unwanted microorganisms. This factor should also be considered in selecting decontamination materials and methods. Refer to Chapter F2 of this manual for specific decontamination procedures.

11.0 Biohazardous Waste Management

Proper handling and management of biohazardous waste is essential to effective exposure control. In general, a program for managing laboratory wastes should have two basic goals:

- To operate the laboratory in compliance with all applicable regulations, guidelines, and good industry practices.
- To manage the wastes in a manner that protects employees, the public, and the environment.

Chapter C14 of this manual provides specific guidance on biohazardous waste management.

12.0 Emergency Procedures/ Spill Response

Emergency procedures for responding to an incident involving biohazards are presented in Chapter G of this manual. Chapter F2 of this manual provides guidelines to assist the PI and other responsible individuals who may be involved in the cleanup of biological spills.

Attachment C7-1: Classifications of Microorganisms Based on Hazard

Purpose: To provide a list of organisms that have been classified on the basis of their hazard.

Instructions: Use this list as a means to determine into what hazard class a microorganism falls.

Class 1 Agents

All bacterial, parasitic, fungal, viral, rickettsial, and chlamydial agents not included in higher classes.

Class 2 Agents

Bacterial Agents

Acinetobacter calcoaceticus
Actinobacillus—all species
Aeromonas hydrophila
Arizona hinshawii—all stereotypes
Bacillus anthracis
Bordetella—all species
Borrelia recurrentis, B. vincenti
Campylobacter fetus
Campylobacter jejuni
Chlamydia psittaci
Chlamydia trachomatis
Clostridium botulinum,
    Cl. chauvoei, Cl. haemolyticum,
    Cl. histolyticum, Cl. novyi,
    Cl. septicum, Cl. tetani
Corynebacterium diphtheriae,
    C. equi, C. haemolyticum,
    C. pseudotuberculosis,
    C. pyogenes, C. renale
Edwardsiella tarda
Erysipelothrix insidiosa
Escherichia coli—all enteropathogenic, enterotoxigenic, enteroinvasive and strains bearing K1 antigen
Haemophilus ducreyi, H. influenzae
Klebsiella—all species and all stereotypes
Legionella pneumophila
Leptospira interrogans—all stereotypes
Listeria—all species
Moraxella—all species
Mycobacteria—all species except those listed in Class 3
Mycoplasma—all species except M. mycoides and M. agalactiae, which are in Class 5
Neisseria gonorrhoeae, N. meningitidis
Pasteurella—all species except those listed in Class 3
Salmonella—all species and serotypes
Shigella—all species and all serotypes
Sphaerophorus necrophorus
Staphylococcus aureus
Streptobacillus moniliformis
Streptococcus pneumoniae
Streptococcus pyogenes
Treponema carateum, T. pallidum and T. pertenue
Vibrio cholerae
Vibrio parahemolyticus
Yersinia enterocolitica

Fungal Agents

Actinomycetes—including Nocardia species, Acinomyces species, and Arachnia propionic
Blastomyces dermatitidis
Cryptococcus neoformans
Paracoccidioides braziliensis

Parasitic Agents

Endamoeba histolytica
Leishmania sp.
Naegleria gruberi
Schistosoma mansoni
Toxoplasma gondii
Toxocara canis
Trichinella spiralis
Trypanosoma cruzi

Viral, Rickettsial, and Chlamydial Agents

Adenoviruses—human—all types
Cache Valley virus
Coxsackie A and B viruses
Cytomegaloviruses
Echoviruses—all types

Encephalomyocarditis virus (EMC)
Flanders virus
Hart Park virus
Hepatitus—associated antigen material
Herpes viruses—except Herpes virus simiae (Monkey B virus) which is in Class 4
Corona viruses
Influenza viruses—all types except A/PR8/34, which is in Class 1
Langat virus
Lymphogranuloma venereum agent
Measles virus
Mumps virus
Parainfluenza virus—all types except Parainfluenza virus 3, SF4 strain, which is in Class 1
Polioviruses—all types, wild and attenuated
Poxviruses—all types except Alastrim, Smallpox, and Whitepox which are in Class 5, and Monkey pox which, depending on experiments, is in Class 3 or 4
Rabies virus—all strains except Rabies street virus which is in Class 3
Reoviruses—all types
Respiratory syncytial virus
Rhinoviruses—all types
Rubella virus
Simian viruses—all types except Herpesvirus simiae (Monkey B virus) and Marburg virus which are in Class 4
Sindbis virus
Tensaw virus
Turlock virus
Vaccinia virus
Varicella virus
Vesicular stomatitis virus
Vole rickettsia
Yellow fever virus, 17D vaccine strain

Class 3 Agents

Bacterial Agents
Bartonella—all species
Brucello—all species
Francisella tuiarensis
Mycobacterium avium, M. bovis, M. tuberculosis
Pasteurella multocide type B ("buffalo" and other foreign virulent strains)
Pseudomonas mallei
Pseudomonas pseudomallei
Yersinia pestis

Fungal Agents
Coccidioides immitis
Histoplasma capsulatum
Histoplasma capsulatum var. duboisii

Parasitic Agents
None

Viral, Rickettsial, and Chlamydial Agents
Monkey pox—when used *in vitro*
Arboviruses—all strains except those in Class 2 and 4 (Arboviruses indigenous to the United States are in Class 3 except those listed in Class 2. West Nile and Semliki Forest viruses may be classified up or down depending on the conditions of use and geographical location of the laboratory.)
Dengue virus—when used for transmis sion or animal inoculation experi-ments
Lymphocytic choriomeningitis virus (LCM)
Rickettsia—all species except Vole rickettsia when used for transmission or animal inoculation experiments
Yellow fever virus—wild—when used *in vitro*

Class 4 Agents

Bacterial Agents
None

Fungal Agents
None

Parasitic Agents
None

Viral, Rickettsial, and Chlamydial Agents
Ebola fever virus
Monkey pox—when used for transmission or animal inoculation experiments
Hemorrhagic fever agents—including Crimean hemorrhagic fever, (Congo), Junin, machupo viruses, and others as yet undefined
Herpesvirus simiae (Monkey B virus)
Lassa virus
Marburg virus
Tick-borne encephalitis virus complex—including Russian spring-summer encephalitis, Kyasanur forest disease, Omsk hemorrhagic fever, and Central European encephalitis viruses
Venezuelan equine encephalitis virus—epidemic strains, when used for transmission or animal inoculation experiments
Yellow fever virus—wild—when used for transmission or animal inoculation experiments

Attachment C7-2: Laboratory Biosafety Level Criteria

Purpose: To provide a detailed discussion of the biosafety level criteria used in a laboratory.

Instructions: Refer to the detailed instructions for safe use of biohazardous agents to supplement current programs.

Biosafety Level 1

Biosafety Level 1 (BL1) is suitable for work involving agents of no known or of minimal potential hazard to laboratory personnel and the environment. The laboratory is not separated from the general traffic patterns in the building. Work is generally conducted on open bench tops. Special containment equipment is not required or generally used. Laboratory personnel have specific training in the procedures conducted in the laboratory and are supervised by a scientist with general training in microbiology or a related science.

The following standard and special practices, safety equipment, and facilities apply to agents assigned to BL1:

A. Standard Microbiological Practices

1. Access to the laboratory is limited or restricted at the discretion of the Laboratory Director when experiments are in progress.

2. Work surfaces are decontaminated once a day and after any spill of viable material.

3. All contaminated liquid or solid wastes are decontaminated before disposal.

4. Mechanical pipetting devices are used; mouth pipetting is prohibited.

5. Eating, drinking, smoking, and applying cosmetics are not permitted in the work area. Cabinets or refrigerators designated and used for food storage are to be located outside of the work area.

6. Persons wash their hands after they handle viable materials and animals and before leaving the laboratory.

7. All procedures are performed carefully to minimize the creation of aerosols.

8. It is recommended that laboratory coats, gowns, or uniforms be worn to prevent contamination or soiling of street clothes.

B. Special Practices

1. Contaminated materials that are to be decontaminated at a site away from the laboratory are placed in a durable, leak-proof container that is closed before being removed from the laboratory.

2. An insect and rodent control program is in effect.

Biosafety Level 1 (continued)

C. Containment Equipment

Special containment equipment is generally not required for manipulations of agents assigned to BL1.

D. Laboratory Facilities

1. The laboratory is designed so that it can be easily cleaned.

2. Bench tops are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.

3. Laboratory furniture is sturdy. Spaces between benches, cabinets, and equipment are accessible for cleaning.

4. Each laboratory contains a sink for hand washing.

5. If the laboratory has windows that open, they are fitted with fly screens.

Biosafety Level 2

Biosafety Level 2 (BL2) is similar to BL1 and is suitable for work involving agents of moderate potential hazard to personnel and the environment. It differs in that (1) laboratory personnel have specific training in handling pathogenic agents and are directed by competent scientists, (2) access to the laboratory is limited when work is being conducted, and (3) certain procedures in which infectious aerosols are created are conducted in biological safety cabinets or other physical containment equipment.

The following standard and special practices, safety equipment, and facilities apply to agents assigned to BL2:

A. Standard Microbiological Practices

1. Access to the laboratory is limited or restricted by the Laboratory Director when work with infectious agents is in progress.

2. Work surfaces are decontaminated at least once a day and after any spill of viable material.

3. All infectious liquid or solid wastes are decontaminated before disposal.

4. Mechanical pipetting devices are used; mouth pipetting is prohibited.

5. Eating, drinking, smoking, and applying cosmetics are not permitted in the work area. Cabinets or refrigerators designated and used for food storage are located outside of the work area.

6. Persons wash their hands after handling infectious materials and animals and when they leave the laboratory.

7. All procedures are performed carefully to minimize the creation of aerosols.

B. Special Practices

1. Contaminated materials that are to be decontaminated at a site away from the laboratory are placed in a durable, leakproof container that is closed before being removed from the laboratory.

Biosafety Level 2 (continued)

2. The Laboratory Director limits access to the laboratory. In general, persons who are at increased risk of acquiring infection or for whom infection may be unusually hazardous are not allowed in the laboratory or animal rooms. The Director has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory.

3. The Laboratory Director establishes policies and procedures whereby only persons who have been advised of the potential hazard and meet any specific entry requirements (e.g., vaccination) enter the laboratory or animal rooms.

4. When the infectious agent(s) in use in the laboratory require special provisions for entry (e.g., vaccination), a hazard warning sign incorporating the universal biohazard symbol is posted on the access door to the laboratory work area. The hazard warning sign identifies the infectious agent, lists the name and telephone number of the Laboratory Director or other responsible person(s), and indicates the special requirement(s) for entering the laboratory.

5. An insect and rodent control program is in effect.

6. Laboratory coats, gowns, smocks, or uniforms are worn while in the laboratory. Before leaving the laboratory for nonlaboratory areas (e.g., cafeteria, library, administrative offices), this protective clothing is removed and left in the laboratory or covered with a clean coat not used in the laboratory.

7. Only animals involved in the work being performed are permitted in the laboratory.

8. Special care is taken to avoid skin contamination with infectious materials. Gloves are worn when handling infected animals and when skin contact with infectious materials is unavoidable.

9. All wastes from laboratories and animal rooms are appropriately decontaminated before disposal.

10. Hypodermic needles and syringes are used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles. Only needle-locking syringes or disposable syringe-needle units (i.e., needle is integral to the syringe) are used for the injection or aspiration of infectious fluids. Extreme caution is used when handling needles and syringes to avoid autoinoculation and the generation of aerosols during use

Biosafety Level 2 (continued)

and disposal. Needles are not bent, sheared, replaced in the sheath or guard or removed from the syringe following use. The needle and syringe are promptly placed in a puncture-resistant container and decontaminated, preferably by autoclaving, before disposal.

11. Spills and accidents that result in overt exposures to infectious materials are immediately reported to the Laboratory Director. Medical evaluation, surveillance, and treatment are provided as appropriate and written records are maintained.

12. When appropriate, considering the agent(s) handled, baseline serum samples for laboratory and other at-risk personnel are collected and stored. Additional serum specimens may be collected periodically, depending on the agents handled or the function of the facility.

13. A biosafety manual is prepared or adopted. Personnel are advised of special hazards and are required to read instructions on practices and procedures and to follow them.

C. Containment Equipment

Biological safety cabinets (Class I or II) or other appropriate personal protective or physical containment devices are used whenever:

1. Procedures with a high potential for creating infectious aerosols are conducted. These may include centrifuging, grinding, blending, vigorous shaking or mixing, sonic disruption, opening containers of infectious materials whose internal pressures may be different from ambient pressures, inoculating animals intranasally, and harvesting infectious tissues from animals or eggs.

2. High concentrations or large volumes of infectious agents are used. Such materials may be centrifuged in the open laboratory if sealed heads or centrifuge safety cups are used and if they are opened only in a biological safety cabinet.

D. Laboratory Facilities

1. The laboratory is designed so that it can be easily cleaned.

2. Bench tops are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.

3. Laboratory furniture is sturdy, and spaces between benches, cabinets, and equipment are accessible for cleaning.

Biosafety Level 2 (continued)

4. Each laboratory contains a sink for hand washing.

5. If the laboratory has windows that open, they are fitted with fly screens.

6. An autoclave for decontaminating infectious laboratory wastes is available.

Biosafety Level 3

Biosafety Level 3 (BL3) is applicable to clinical, diagnostic, teaching, research, or production facilities in which work is done with dangerous or exotic agents that may cause serious or potentially lethal disease as a result of exposure by inhalation. Laboratory personnel have specific training in handling pathogenic and potentially lethal agents and are supervised by competent scientists who are experienced in working with these agents. All procedures involving the manipulation of infectious material are conducted within biological safety cabinets or other physical containment devices or by personnel wearing appropriate personal protective clothing and devices.

The laboratory has special engineering and design features. It is recognized, however, that many existing facilities may not have all the facility safeguards recommended for BL3 (e.g., access zone, sealed penetrations, and directional airflow, etc.). In these circumstances, acceptable safety may be achieved for routine tasks or repetitive operations (e.g., diagnostic procedures involving the propagation of an agent for identification, typing, and susceptibility testing) in laboratories where facility features satisfy BL2 recommendations provided the recommended "Standard Microbiological Practices," "Special Practices," and "Containment Equipment" for BL3 are rigorously followed. The decision to implement this modification of BL3 recommendations should be made only by the Laboratory Director.

The following standard and special safety practices, equipment, and facilities apply to agents assigned to BL3:

A. Standard Microbiological Practices

1. Work surfaces are decontaminated at least once a day and after any spill of viable material.

2. All infectious liquid or solid wastes are decontaminated before disposal.

3. Mechanical pipetting devices are used; mouth pipetting is prohibited.

4. Eating, drinking, smoking, storing food, and applying cosmetics are not permitted in the work area.

5. Persons wash their hands after handling infectious materials and animals and when they leave the laboratory.

6. All procedures are performed carefully to minimize the creation of aerosols.

Biosafety Level 3 (continued)

B. Special Practices

1. Laboratory doors are kept closed when experiments are in progress.

2. Contaminated materials that are to be decontaminated at a site away from the laboratory are placed in a durable, leak-proof container which is closed before being removed from the laboratory.

3. The Laboratory Director controls access to the laboratory and restricts access to persons whose presence is required for program or support purposes. Persons who are at increased risk of acquiring infection or for whom infection may be unusually hazardous are not allowed in the laboratory or animal rooms. The Director has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory.

4. The Laboratory Director establishes policies and procedures whereby only persons who have been advised of the potential biohazard, who meet any specific entry requirements (e.g., vaccination), and who comply with all entry and exit procedures enter the laboratory or animal rooms.

5. When infectious materials or infected animals are present in the laboratory or containment module, a hazard warning sign incorporating the universal biohazard symbol is posted on all laboratory and animal room access doors. The hazard warning sign identifies the agent, lists the name and telephone number of the Laboratory Director or other responsible person(s), and indicates any special requirements for entering the laboratory, such as the need for vaccinations, respirators, or other personal protective measures.

6. All activities involving infectious materials are conducted in biological safety cabinets or other physical containment devices within the containment module. No work in open vessels is conducted on the open bench.

7. The work surfaces of biological safety cabinets and other containment equipment are decontaminated when work with infectious materials is finished. Plastic-backed paper toweling used on nonperforated work surfaces within biological safety cabinets facilitates cleanup.

8. An insect and rodent control program is in effect.

Biosafety Level 3 (continued)

9. Laboratory clothing that protects street clothing (e.g., solid front or wrap-around gowns, scrub suits, overalls) is worn in the laboratory. Laboratory clothing is not worn outside the laboratory, and it is decontaminated before being laundered.

10. Special care is taken to avoid skin contamination with infectious materials. Gloves are worn when handling infected animals and when skin contact with infectious materials is unavoidable.

11. Molded surgical masks or respirators are worn in rooms containing infected animals.

12. Only animals and plants related to the work being conducted are permitted in the laboratory.

13. All wastes from laboratories and animal rooms are appropriately decontaminated before disposal.

14. Vacuum lines are protected with high-efficiency particulate air (HEPA) filters and liquid disinfectant traps.

15. Hypodermic needles and syringes are used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles. Only needle-locking syringes or disposable syringe-needle units (i.e., needle is integral to the syringe) are used for the injection or aspiration of infectious fluids. Extreme caution is used when handling needles and syringes to avoid autoinoculation and the generation of aerosols during use and disposal. Needles are not bent, sheared, replaced in the sheath or guard, or removed from the syringe following use. The needle and syringe should be promptly placed in a puncture-resistant container and decontaminated, preferably by autoclaving, before disposal.

16. Spills and accidents that result in overt or potential exposures to infectious materials are immediately reported to the Laboratory Director. Appropriate medical evaluation, surveillance, and treatment are provided and written records are maintained.

17. Baseline serum samples for all laboratory and other at-risk personnel are collected and stored. Additional serum specimens may be collected periodically, depending on the agents handled or the function of the laboratory.

18. A biosafety manual is prepared or adopted. Personnel are advised of special hazards and are required to read instructions on practices and procedures and to follow them.

Biosafety Level 3 (continued)

C. Containment Equipment

Biological safety cabinets (Class I, II, or III) or other appropriate combinations of personal protective or physical containment devices (e.g., special protective clothing, masks, gloves, respirators, centrifuge safety cups, sealed centrifuge rotors, and containment caging for animals) are used for all activities with infectious materials that pose a threat of aerosol exposure. These include: manipulation of cultures and of those clinical or environmental materials that may be a source of infectious aerosols; the aerosol challenge of experimental animals; harvesting of tissues or fluids from infected animals and embryonated eggs, and necropsy of infected animals.

D. Laboratory Facilities

1. The laboratory is separated from areas that are open to unrestricted traffic flow within the building. Passage through two sets of doors is the basic requirement for entry into the laboratory from access corridors or other contiguous areas. Physical separation of the high-containment laboratory from access corridors or other laboratories or activities may also be provided by a double-doored clothes change room (showers may be included), airlock, or other access facility that requires passage through two sets of doors before entering the laboratory.

2. The interior surfaces of walls, floors, and ceilings are water resistant so that they can be easily cleaned. Penetrations in these surfaces are sealed or capable of being sealed to facilitate decontaminating the area.

3. Bench tops are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.

4. Each laboratory contains a sink for hand washing. The sink is foot-, elbow-, or automatically operated and is located near the laboratory exit door.

5. Windows in the laboratory are closed and sealed.

6. Access doors to the laboratory or containment module are self-closing.

7. An autoclave for decontaminating laboratory wastes is available, preferably within the laboratory.

Biosafety Level 3 (continued)

8. A ducted exhaust air ventilation system is provided. This system creates directional airflow that draws air into the laboratory through the entry areas. The exhaust air is not recirculated to any other area of the building, is discharged to the outside, and is dispersed away from occupied areas and air intakes. Personnel must verify that the direction of the airflow (into the laboratory) is proper. The exhaust air from the laboratory room can be discharged to the outside without being filtered or otherwise treated.

9. The HEPA-filtered exhaust air from Class I or Class II biological safety cabinets is discharged directly to the outside or through the building exhaust system. Exhaust air from Class I or Class II biological safety cabinets may be recirculated within the laboratory if the cabinet is tested and certified at least every 12 months. If the HEPA-filtered exhaust air from Class I or II biological safety cabinets is to be discharged to the outside through the building exhaust air system, it is connected to this system in a manner (e.g., thimble unit connection) that avoids any interference with the air balance of the cabinets or building exhaust system.

Biosafety Level 4

Biosafety Level 4 (BL4) is required for work with dangerous and exotic agents that pose a high individual risk of life-threatening disease. Members of the laboratory staff have specific and thorough training in handling extremely hazardous infectious agents, and they understand the primary and secondary containment functions of the standard and special practices, the containment equipment, and the laboratory design characteristics. They are supervised by competent scientists who are trained and experienced in working with these agents. Access to the laboratory is strictly controlled by the Laboratory Director. The facility is either in a separate building or in a controlled area within a building, which is completely isolated from all other areas of the building. A specific facility operations manual is prepared or adopted.

Within work areas of the facility, all activities are confined to Class III biological safety cabinets or Class I or Class II biological safety cabinets used along with one-piece positive-pressure personnel suits ventilated by a life support system. The maximum containment laboratory has special engineering and design features to prevent microorganisms from being disseminated into the environment.

The following standard and special safety practices, equipment, and facilities apply to agents assigned to BL4:

A. Standard Microbiological Practices

1. Work surfaces are decontaminated at least once a day and immediately after any spill of viable material.

2. Only mechanical pipetting devices are used.

3. Eating, drinking, smoking, storing food, and applying cosmetics are not permitted in the laboratory.

4. All procedures are performed carefully to minimize the creation of aerosols.

B. Special Practices

1. Biological materials to be removed from the Class III biological safety cabinet or from the maximum containment laboratory in a viable or intact state are transferred to a nonbreakable, sealed primary container and then enclosed in a nonbreakable, sealed secondary container which is removed from the facility through a disinfectant dunk tank, fumigation chamber, or an airlock designed for this purpose.

Biosafety Level 4 (continued)

2. No materials, except for biological materials that are to remain in a viable or intact state, are removed from the maximum containment laboratory unless they have been autoclaved or decontaminated before they leave the facility. Equipment or material that might be damaged by high temperatures or steam is decontaminated by gaseous or vapor methods in an airlock or chamber designed for this purpose.

3. Only essential personnel are authorized to enter a BL4 laboratory. Those who may be at increased risk of acquiring infection or for whom infection may be unusually hazardous are not allowed in the laboratory or animal rooms. The supervisor has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory.

   Laboratory access is limited by means of secure, locked doors. Accessibility is managed by the Laboratory Director, biosafety officer, or other person responsible for the physical security of the facility. Before entering, persons are advised of the potential biohazards and instructed as to appropriate safeguards for ensuring their safety. Authorized persons comply with the instructions and all other applicable entry and exit procedures. A logbook, signed by all personnel, indicates the date and time of each entry and exit. Practical and effective protocols for emergency situations are established.

4. Personnel enter and leave the facility only through the clothing change and shower rooms. Personnel shower each time they leave the facility. Personnel use the airlocks to enter or leave the laboratory only in an emergency.

5. Street clothing is removed in the outer clothing change room and kept there. Complete laboratory clothing (e.g., undergarments, pants and shirts or jumpsuits, shoes and gloves) is provided and used by all personnel entering the facility. Head covers are provided for personnel who do not wash their hair during the exit shower. When leaving the laboratory and before proceeding into the shower area, personnel remove their laboratory clothing and store it in a locker or hamper in the inner change room.

6. When infectious materials or infected animals are present in the laboratory or animal rooms, a hazard warning sign incorporating the universal biohazard symbol is posted on all access doors. The sign identifies the agent, lists the name of the Laboratory Director or other responsible person(s), and indicates any special requirements for entering the area (e.g., the need for vaccinations or respirators).

Biosafety Level 4 (continued)

7. Supplies and materials needed in the facility are brought in by way of the double-doored autoclave, fumigation chamber, or airlock, which is appropriately decontaminated after each use. After securing the outer doors, personnel within the facility retrieve the materials by opening the interior doors of the autoclave, fumigation chamber, or airlock. These doors are secured after materials are brought into the facility.

8. An insect and rodent control program is in effect.

9. Only materials related to the experiment being conducted are permitted in the facility.

10. Hypodermic needles and syringes are used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles. Only needle-locking syringes or disposable syringe-needle units (i.e., needle is integral part of unit) are used for the injection or aspiration of infectious fluids. Needles should not be bent, sheared, replaced in the needle guard, or removed from the syringe following use. The needle and syringe should be placed in a puncture-resistant container and decontaminated, preferably by autoclaving, before disposal. Whenever possible, cannulas are used instead of sharp needles (e.g., gavage).

11. A system is set up for reporting laboratory accidents and exposures and employee absenteeism, and for the medical surveillance of potential laboratory-associated illnesses. Written records are prepared and maintained. An essential adjunct to such a reporting/surveillance system is the availability of a facility for the quarantine, isolation, and medical care of personnel with potential or known laboratory-associated illnesses.

C. Containment Equipment

All procedures within the facility with agents assigned to biosafety level 4 are conducted in a Class III biological safety cabinet or in Class I or II biological safety cabinets used in conjunction with one-piece positive-pressure personnel suits ventilated by a life support system. Activities with viral agents (e.g., Rift Valley fever virus) that require biosafety level 4 secondary containment capabilities and for which highly effective vaccines are available and used can be conducted within Class I or Class II biological safety cabinets within the facility without the one-piece positive-pressure personnel suit being used if: (1) the facility has been decontaminated, (2) no work is being conducted in the facility with other agents assigned to biosafety level 4, and (3) all other standard and special practices are followed.

Biosafety Level 4 (continued)

D. Laboratory Facility

1. The maximum containment facility consists of either a separate building or a clearly demarcated and isolated zone within a building. Outer and inner change rooms separated by a shower are provided for personnel entering and leaving the facility. A double-doored autoclave, fumigation chamber, or ventilated airlock is provided for passage of those materials, supplies, or equipment that are not brought into the facility through the change room.

2. Walls, floors, and ceilings of the facility are constructed to form a sealed internal shell that facilitates fumigation and is animal- and insect-proof. The internal surfaces of this shell are resistant to liquids and chemicals, thus facilitating cleaning and decontamination of the area. All penetrations in these structures and surfaces are sealed. Any drains in the floors contain traps filled with a chemical disinfectant of demonstrated efficacy against the target agent, and are connected directly to the liquid waste decontamination system. Sewer and other ventilation lines contain HEPA filters.

3. Internal facility appurtenances, such as light fixtures, air ducts, and utility pipes, are arranged to minimize the horizontal surface area on which dust can settle.

4. Bench tops have seamless surfaces that are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.

5. Laboratory furniture is of simple and sturdy construction, and spaces between benches, cabinets, and equipment are accessible for cleaning.

6. A foot-, elbow-, or automatically-operated handwashing sink is provided near the door of each laboratory room in the facility.

7. If there is a central vacuum system, it does not serve areas outside the facility. In-line HEPA filters are placed as near as practical to each use point or service cock. Filters are installed to permit in-place decontamination and replacement. Other liquid and gas services to the facility are protected by devices that prevent backflow.

8. If water fountains are provided, they are foot-operated and are located in the facility corridors outside the laboratory. The water service to the fountain is not connected to the backflow-protected distribution system supplying water to the laboratory areas.

9. Access doors to the laboratory are self-closing and lockable.

10. Any windows are breakage resistant.

Biosafety Level 4 (continued)

11. A double-doored autoclave is provided for decontaminating materials passing out of the facility. The autoclave door that opens to the area external to the facility is sealed to the outer wall and automatically controlled so that the outside door can only be opened after the autoclave "sterilization" cycle has been completed.

12. A pass-through dunk tank, fumigation chamber, or an equivalent decontamination method is provided so that materials and equipment that cannot be decontaminated in the autoclave can be safely removed from the facility.

13. Liquid effluents from laboratory sinks, biological safety cabinets, floors, and autoclave chambers are decontaminated by heat treatment before being released from the rooms. Toilets may be decontaminated with chemical disinfectants or by heat in the liquid waste decontamination system. The procedures used for heat decontamination of liquid wastes is evaluated mechanically and biologically by using a recording thermometer and an indicator microorganism with a defined heat susceptibility pattern. If liquid wastes from the shower rooms are decontaminated with chemical disinfectants, the chemical used is of demonstrated efficacy against the target or indicator microorganisms.

14. An individual supply and exhaust air ventilation system is provided. The system maintains pressure differentials and directional airflow as required to ensure flow inward from areas outside of the facility toward areas of highest potential risk within the facility. Manometers are used to sense pressure differentials between adjacent areas maintained at different pressure levels. If a system malfunctions, the manometers sound an alarm. The supply and exhaust airflow is interlocked to ensure inward (or zero) airflow at all times.

15. The exhaust air from the facility is filtered through HEPA filters and discharged to the outside so that it is dispersed away from occupied buildings and air intakes. Within the facility, the filters are located as near the laboratories as practical in order to reduce the length of potentially contaminated air ducts. The filter chambers are designed to allow *in situ* decontamination before filters are removed and to facilitate certification testing after they are replaced. Coarse filters and HEPA filters are provided to treat air supplied to the facility in order to increase the lifetime of the exhaust HEPA filters and to protect the supply air system should air pressures become unbalanced in the laboratory.

16. The treated exhaust air from Class I and II biological safety cabinets can be discharged into the laboratory room environment or to the outside through the facility air exhaust system. If exhaust air from Class I or II biological safety cabinets is discharged into the laboratory, the cabinets are tested and certified at six-month intervals. *The treated exhausted air from Class III biological safety cabinets is discharged, without recirculation, through two sets of HEPA filters in series, via the facility exhaust air system.* If the treated exhaust air from any of these cabinets is discharged to the outside through the

Biosafety Level 4 (continued)

facility exhaust air system, it is connected to this system in a manner (e.g., thimble unit connection) that avoids any interference with the air balance of the cabinets or the facility exhaust air system.

17. A specially designed suit area may be provided in the facility. Personnel who enter this area wear a one-piece positive-pressure suit that is ventilated by a life-support system. The life support system includes alarms and emergency backup breathing air tanks. Entry to this area is through an airlock fitted with airtight doors. A chemical shower is provided to decontaminate the surface of the suit before the worker leaves the area. The exhaust air from the suit area is filtered by two sets of HEPA filters installed in series. A duplicate filtration unit, exhaust fan, and an automatically starting emergency power source are provided. The air pressure within the suit area is lower than that of any adjacent area. Emergency lighting and communication systems are provided. All penetrations into the internal shell of the suit area are sealed. A double-doored autoclave is provided for decontaminating waste materials to be removed from the suit area.

Attachment C7-3: Laboratory Animal Biosafety Level Criteria

Purpose: To provide a detailed discussion of the animal biosafety level criteria used in a laboratory.

Instructions: Refer to the detailed instructions for safe use laboratory animals to supplement current programs.

Animal Biosafety Level 1

Animal biosafety level 1 (ABSL1) is suitable for work involving agents of no known or of minimal potential hazard to laboratory personnel and the environment. Special containment equipment is not required or generally used. Laboratory personnel have specific training in the animal handling and experimental procedures and are supervised by a scientist with appropriate training.

The following standard and special practices, containment equipment and facilities apply to animals assigned to ABSL1:

A. Standard Practices

1. Doors to animal rooms open inward, are self-closing, and are kept closed when experimental animals are present.

2. Work surfaces are decontaminated after use or after any spill of viable materials.

3. Eating, drinking, smoking, and storing food for human use are not permitted in animal rooms.

4. Personnel wash their hands after handling cultures and animals and before leaving the animal room.

5. All procedures are carefully performed to minimize the creation of aerosols.

6. An insect and rodent control program is in effect.

B. Special Practices

1. Bedding materials from animal cages are removed in such a manner as to minimize the creation of aerosols, and are disposed of in compliance with applicable institutional or local requirements.

2. Cages are washed manually or in a cagewasher. Temperature of final rinse water in a mechanical washer should be 180°F.

3. The wearing of laboratory coats, gowns, or uniforms in the animal room is recommended. It is further recommended that laboratory coats worn in the animal room not be worn in other areas.

Animal Biosafety Level 1 (continued)

C. Containment Equipment

Special containment equipment is not required for animals infected with agents assigned to ABSL1.

D. Animal Facilities

1. The animal facility is designed and constructed to facilitate cleaning and housekeeping.

2. A handwashing sink is available in the animal facility.

3. If the animal facility has windows that open, they are fitted with fly screens.

4. It is recommended, but not required, that the direction of airflow in the animal facility is inward and that exhaust air is discharged to the outside without being recirculated to other rooms.

Animal Biosafety Level 2

Animal biosafety level 2 (ABSL2) is similar to level 1 and is suitable for work involving agents of moderate potential hazard to personnel and the environment. It differs in that (1) access to the laboratory is limited when work is being conducted, (2) laboratory personnel have specific training on handling infectious animals and are directed by competent scientists, and (3) certain procedures in which infectious aerosols are created are conducted in biological safety cabinets or other physical containment.

The following standard and special practices, containment equipment, and facilities apply to animals assigned to ABSL2:

A. Standard Practices

1. Doors to animal rooms open inward, are self-closing, and are kept closed when infected animals are present.

2. Work surfaces are decontaminated after use or spills of viable materials.

3. Eating, drinking, smoking, and storing of food for human use are not permitted in animal rooms.

4. Personnel wash their hands after handling cultures and animals and before leaving the animal room.

5. All procedures are carefully performed to minimize the creation of aerosols.

6. An insect and rodent control program is in effect.

B. Special Practices

1. Cages are decontaminated, preferably by autoclaving, before they are cleaned and washed.

2. Surgical-type masks are worn by all personnel entering animal rooms housing nonhuman primates.

3. Laboratory coats, gowns, or uniforms are worn while in the animal rooms. This protective clothing is removed before leaving the animal facility.

Animal Biosafety Level 2 (continued)

4. The Laboratory Director or Animal Facility Manager limits access to the animal rooms to personnel who have been advised of the potential hazard and who need to enter the room for program or service purposes when work is in progress. In general, persons who may be at increased risk of acquiring infection or for whom infection might be unusually hazardous are not allowed in the animal rooms.

5. The Laboratory Director or Animal Facility Manager establishes policies and procedures whereby only persons who have been advised of the potential hazard and meet any specific requirements (e.g., vaccination) may enter the animal room.

6. When the infectious agent(s) in use in the animal room requires special entry provisions (e.g., vaccination), a hazard warning sign incorporating the universal biohazard symbol is posted on the access door to the animal room. The hazard warning sign identifies the infectious agent, lists the name and telephone number of the animal facility supervisor or other responsible person(s), and indicates the special requirement(s) for entering the animal room.

7. Special care is taken to avoid skin contamination with infectious materials. Gloves should be worn when handling infected animals and when skin contact with infectious materials is unavoidable.

8. All wastes from the animal room are appropriately decontaminated, preferably by autoclaving, before disposal. Infected animal carcasses are incinerated after being transported from the animal room in leakproof, covered containers.

9. Hypodermic needles and syringes are used only for the parenteral injection or aspiration of liquids from laboratory animals and diaphragm bottles. Only needle-locking syringes or disposable needle syringe units (i.e., the needle is integral to the syringe) are used for the injection or aspiration of infectious fluids. Needles are not bent, sheared, replaced in the sheath or guard or removed from the syringe following use. The needle and syringe are promptly placed in a puncture-resistant container and decontaminated, preferably by autoclaving, before disposal.

10. If floor drains are provided, the drain traps are always filled with water or a suitable disinfectant.

11. When appropriate, considering the agents handled, baseline serum samples from animal care and other at-risk personnel are collected and stored. Additional serum samples may be collected periodically, depending on the agents handled or the function of the facility.

Animal Biosafety Level 2 (continued)

C. Containment Equipment

Biological safety cabinets, other physical containment devices, and/or personal protective devices (e.g., respirators, face shields) are used whenever procedures with a high potential for creating aerosols are conducted. These include necropsy of infected animals, harvesting of infected tissues or fluids from animals or eggs, intranasal inoculation of animals, and manipulations of high concentrations or large volumes of infectious materials.

D. Animal Facilities

1. The animal facility is designed and constructed to facilitate cleaning and housekeeping.

2. A handwashing sink is available in the room where infected animals are housed.

3. If the animal facility has windows that open, they are fitted with fly screens.

4. It is recommended, but not required, that the direction of airflow in the animal facility is inward and that exhaust air is discharged to the outside without being recirculated to other rooms.

5. An autoclave capable of decontaminating infectious laboratory waste is available in the building with the animal facility.

Animal Biosafety Level 3

Animal biosafety Level 3 (ABSL3) is applicable to clinical, diagnostic, teaching, research, or production facilities in which work is done with dangerous or exotic agents that may cause serious or potentially lethal disease as a result of exposure by inhalation. Laboratory personnel have specific training in handling pathogenic and potentially lethal agents and are supervised by competent scientists who are experienced in working with these agents. All procedures involving the manipulation of infectious material are conducted within biological safety cabinets or other physical containment devices or by personnel wearing appropriate personal protective clothing and devices.

The animal facility also has special design features such as: automatically operated hand-washing sinks, exhaust air ventilation system, and HEPA-filtered exhaust air from primary containment devices.

The following standard and special safety practices, containment equipment, and facilities apply to animals assigned to animal ABSL3:

A. Standard Practices

1. Doors to animal rooms open inward, are self-closing, and are kept closed when work with infected animals is in progress.

2. Work surfaces are decontaminated after use or spills of viable materials.

3. Eating, drinking, smoking, and storing of food for human use are not permitted in the animal rooms.

4. Personnel wash their hands after handling cultures and animals and before leaving the laboratory.

5. All procedures are carefully performed to minimize the creation of aerosols.

6. An insect and rodent control program is in effect.

B. Special Practices

1. Cages are autoclaved before bedding is removed and before they are cleaned and washed.

2. Surgical-type masks or other respiratory protection devices (e.g., respirators) are worn by personnel entering rooms housing animals infected with agents assigned to ABSL3.

Animal Biosafety Level 3 (continued)

3. Wrap-around or solid-front gowns or uniforms are worn by personnel entering the animal rooms. Front-button laboratory coats are not suitable. Protective gowns must remain in the animal rooms and must be decontaminated before being laundered.

4. The Laboratory Director or other responsible person restricts access to the animal rooms to personnel who have been advised of the potential hazard and who need to enter the rooms for program or service purposes when infected animals are present. In general, persons who may be at increased risk of acquiring infection or for whom infection might be unusually hazardous are not allowed in the animal rooms.

5. The Laboratory Director or other responsible person establishes policies and procedures whereby only persons who have been advised of the potential hazard and meet any specific requirements (e.g., vaccination) may enter the animal rooms.

6. Hazard warning signs incorporating the universal biohazard warning symbol are posted on access doors to animal rooms containing animals infected with agents assigned to biosafety level 3. The hazard warning sign should identify the agent(s) in use, list the name and telephone number of the animal room supervisor or other responsible person(s), and indicate any special conditions of entry into the animal room (e.g., the need for vaccinations or respirators).

7. Personnel wear gloves when handling infected animals. Gloves are removed aseptically and autoclaved with other animal room wastes before being disposed of or reused.

8. All wastes from the animal rooms are autoclaved before disposal. All animal carcasses are incinerated. Dead animals are transported from the animal rooms to the incinerator in leakproof covered containers.

9. Hypodermic needles and syringes are used only for gavage or for parenteral injection or aspiration of fluids from laboratory animals and diaphragm bottles. Only needle-locking syringes or disposable needle syringe units (i.e., the needle is integral to the syringe) are used. Needles are not bent, sheared, replaced in the sheath or guard, or removed from the syringe following use. The needle and syringe are promptly placed in a puncture-resistant container and decontaminated, preferably by autoclaving, before disposal. Whenever possible, cannulas are to be used instead of sharp needles (e.g., gavage).

10. If floor drains are provided, the drain traps are always filled with water or a suitable disinfectant.

11. If vacuum lines are provided, they are protected with HEPA filters and liquid disinfectant traps.

Animal Biosafety Level 3 (continued)

12. Boots, shoe covers, or other protective footwear and disinfectant footbaths are available and used when indicated.

C. Containment Equipment

1. Personal protective clothing and equipment and/or other physical containment devices are used for all procedures and manipulations of infectious materials or infected animals.

2. The risk of infectious aerosols from infected animals or their bedding can be reduced if animals are housed in partial containment caging systems, such as open cages placed in ventilated enclosures (e.g., laminar flow cabinets), solid-wall and -bottom cages covered by filter bonnets, or other equivalent primary containment systems.

D. Animal Facilities

1. The animal facility is designed and constructed to facilitate cleaning and housekeeping and is separated from areas that are open to unrestricted personnel traffic within the building. Passage through two sets of doors is the basic requirement for entry into the animal room from access corridors or other contiguous areas. Physical separation of the animal room from access corridors or other activities may also be provided by a double-doored clothes change room (showers may be included), airlock, or other facility access requiring passage through two sets of doors before entering the animal room.

2. The interior surfaces of walls, floors, and ceilings are water resistant so that they may be easily cleaned. Penetrations in these surfaces are sealed or capable of being sealed to facilitate fumigation or space decontamination.

3. A foot-, elbow-, or automatically-operated handwashing sink is provided near each animal room exit door.

4. Windows in the animal room are closed and sealed.

5. Animal room doors are self-closing and are kept closed when infected animals are present.

6. An autoclave for decontaminating wastes is available, preferably within the animal room. Materials to be autoclaved outside the animal room are transported in a covered leakproof container.

Animal Biosafety Level 3 (continued)

7. An exhaust air ventilation system is provided. This system creates directional air that draws air into the animal room through the entry area. The building exhaust can be used for this purpose if the exhaust air is not recirculated to any other area of the building, is discharged to the outside, and is dispersed away from occupied areas and air intakes. Personnel must verify that the direction of the airflow (into the animal room) is proper. Animal room exhaust air that does not pass through biological safety cabinets or other primary containment equipment can be discharged to the outside without being filtered or otherwise treated.

8. The HEPA-filtered exhaust air from Class I or Class II biological safety cabinets or other primary containment devices is discharged directly to the outside or through the building exhaust system. Exhaust air from these primary containment devices may be recirculated within the animal room if the cabinet is tested and certified at least every 12 months. If the HEPA filtered exhaust air from Class I or Class II biological safety cabinets is discharged to the outside through the building exhaust system, it is connected to this system in a manner (e.g., thimble unit connection) that avoids any interference with the air balance of the cabinets or building exhaust system.

Animal Biosafety Level 4

Animal biosafety Level 4 (ABSL4) is required for work with dangerous and exotic agents that pose a high individual risk of life-threatening disease. Members of the laboratory staff have specific and thorough training in handling extremely hazardous infectious agents, and they understand the primary and secondary containment functions of the standard and special practices, the containment equipment, and the laboratory design characteristics. They are supervised by competent scientists who are trained and experienced in working with these agents. Access to the laboratory is strictly controlled by the Laboratory Director. The facility is either in a separate building or in a controlled area within a building, which is completely isolated from all other areas of the building. A specific facility operations manual is prepared or adopted.

Within work areas of the facility, all activities are confined to Class III biological safety cabinets or in partial containment caging systems used along with one-piece positive-pressure suits ventilated by a life support system.

The following standard and special safety practices, containment equipment, and facilities apply to animals assigned to ABSL4:

A. Standard Practices

1. Doors to animal rooms open inward and are self-closing.

2. Work surfaces are decontaminated after use or spills of viable materials.

3. Eating, drinking, smoking, and storing of food for human use is not permitted in the animal room.

4. An insect and rodent control program is in effect.

5. Cages are autoclaved before bedding is removed and before they are cleaned and washed.

B. Special Practices

1. Only persons whose entry into the facility or individual animal rooms is required for program or support purposes are authorized to enter. Persons who may be at increased risk of acquiring infection or for whom infection might be unusually hazardous are not allowed in the animal facility. Persons at increased risk may include children, pregnant women, and persons who are immunodeficient or immunosuppressed. The supervisor has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory. Access to the facility is limited by secure, locked doors. Accessibility is controlled by the Animal Facility Manager, biohazards control officer, or

Animal Biosafety Level 4 (continued)

other person responsible for the physical security of the facility. Before entering, persons are advised of the potential biohazards and instructed as to appropriate safeguards. Personnel comply with the instructions and all other applicable entry and exit procedures. Practical and effective protocols for emergency situations are established.

2. Personnel enter and leave the facility only through the clothing change and shower rooms. Personnel shower each time they leave the facility. Head covers are provided to personnel who do not wash their hair during the exit shower. Except in an emergency, personnel do not enter or leave the facility through the airlocks.

3. Street clothing is removed in the outer clothing-change room and kept there. Complete laboratory clothing (e.g., undergarments, pants and shirts or jumpsuits, shoes, and gloves), are provided and used by all personnel entering the facility. When exiting, personnel remove laboratory clothing and store it in a locker or hamper in the inner change room before entering the shower area.

4. When infectious materials or infected animals are present in the animal rooms, a hazard warning sign incorporating the universal biohazard symbol is posted on all access doors. The sign identifies the agent, lists the name and telephone number of the animal facility supervisor or other responsible person(s), and indicates any special conditions of entry into the area (e.g., vaccinations and respirators).

5. Supplies and materials to be taken into the facility enter by way of the double-door autoclave, fumigation chamber, or airlock, which is appropriately decontaminated between each use. After securing the outer doors, personnel inside the facility retrieve the materials by opening the interior doors of the autoclave, fumigation chamber, or airlock. This inner door is secured after materials are brought into the facility.

6. Only materials related to the experiment are permitted in the facility.

7. Hypodermic needles and syringes are used only for gavage or for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles. Only needle-locking syringes or disposable needle syringe units (i.e., needle is integral part of unit) are used. Needles should not be bent, sheared, replaced in the guard or sheath, or removed from the syringe following use. The needle and syringe should be promptly placed in a puncture-resistant container and decontaminated, preferably by autoclaving, before disposal. Whenever possible, cannulas should be used instead of sharp needles (e.g., gavage).

Animal Biosafety Level 4 (continued)

8. A system is developed and is operational for the reporting of animal facility accidents and exposures, employee absenteeism, and for the medical surveillance of potential laboratory-associated illnesses. An essential adjunct to such a reporting-surveillance system is the availability of a facility for the quarantine, isolation, and medical care of persons with potential or known laboratory-associated illnesses.

9. Baseline serum samples are collected and stored for all laboratory and other at-risk personnel. Additional serum specimens may be collected periodically, depending on the agents handled or the function of the laboratory.

C. Containment Equipment

Laboratory animals infected with agents assigned to ABSL4 are housed in Class III biological safety cabinets or in partial containment caging systems (such as open cages placed in ventilated enclosures, solid-wall and -bottom cages covered with filter bonnets, or other equivalent primary containment systems) in specially designed areas in which all personnel are required to wear one-piece positive-pressure suits ventilated with a life support system. Animal work with viral agents that require ABSL4 secondary containment and for which highly effective vaccines are available and used, may be conducted with partial-containment cages and without the one-piece positive-pressure personnel suit: (1) if the facility has been decontaminated, (2) no concurrent experiments requiring ABSL4 primary and secondary containment are being done in the facility, and (3) all other standard and special practices are followed.

D. Animal Facility

1. The animal rooms are located in a separate building or in a clearly demarcated and isolated zone within a building. Outer and inner change rooms separated by a shower are provided for personnel entering and leaving the facility. A double-door autoclave, fumigation chamber, or ventilated airlock is provided for passage of materials, supplies, or equipment that are not brought into the facility through the change room.

2. Walls, floors, and ceilings of the facility are constructed to form a sealed internal shell that facilitates fumigation and is animal- and insect-proof. The internal surfaces of this shell are resistant to liquids and chemicals, thus facilitating cleaning and decontamination of the area. All penetrations in these structures and surfaces are sealed.

3. Internal facility appurtenances, such as light fixtures, air ducts, and utility pipes, are arranged to minimize the horizontal surface area on which dust can settle.

Animal Biosafety Level 4 (continued)

4. A foot-, elbow-, or automatically-operated handwashing sink is provided near the door of each animal room within the facility.

5. If there is a central vacuum system, it does not serve areas outside of the facility. The vacuum system has in-line HEPA filters placed as near as practical to each use point or service cock. Filters are installed to permit in-place decontamination and replacement. Other liquid and gas services for the facility are protected by devices that prevent backflow.

6. External animal facility doors are self-closing and self-locking.

7. Any windows must be resistant to breakage and sealed.

8. A double-doored autoclave is provided for decontaminating materials that leave the facility. The autoclave door that opens to the area outside the facility is automatically controlled so that it can be opened after the autoclave "sterilization" cycle is completed.

9. A pass-through dunk tank, fumigation chamber, or equivalent decontamination method is provided so that materials and equipment that cannot be decontaminated in the autoclave can be safety removed from the facility.

10. Liquid effluents from laboratory sinks, cabinets, floors, and autoclave chambers are decontaminated by heat treatment before being discharged. Liquid wastes from shower rooms and toilets may be decontaminated with chemical disinfectants or by heat in the liquid-waste decontamination system. The procedure used for heat decontamination of liquid wastes must be evaluated mechanically and biologically by using a recording thermometer and an indicator microorganism with a defined heat susceptibility pattern. If liquid wastes from the shower rooms are decontaminated with chemical disinfectants, the chemicals used must have documented efficacy against the target or indicator microorganisms.

11. An individual supply and exhaust air ventilation system is provided. The system maintains pressure differentials, and directional airflow is required to ensure inflow from areas outside of the facility toward areas of highest potential risk within the facility. Manometers are provided to sense pressure differentials between adjacent areas that are maintained at different pressure levels. The manometers sound an alarm when a system malfunctions. The supply and exhaust airflow is interlocked to ensure inward (or zero) airflow at all times.

Animal Biosafety Level 4 (continued)

12. The exhaust air from the facility is filtered by HEPA filters and discharged to the outside so that it is dispersed away from occupied buildings and air intakes. Within the facility, the filters are located as near to the laboratories as practical in order to reduce the length of potentially contaminated air ducts. The filter chambers are designed to allow *in situ* decontamination before filters are removed and to facilitate certification testing after they are replaced. Coarse filters are provided for treatment of air supplied to the facility in order to increase the lifetime of the HEPA filters.

13. The treated exhaust air from Class I or Class II biological safety cabinets can be discharged into the animal room environment or to the outside through the facility air exhaust system. If exhaust air from Class I or II biological safety cabinets is discharged into the animal room, the cabinets are tested and certified at six-month intervals. The treated exhaust air from Class III biological safety cabinets is discharged without recirculation via the facility exhaust air system. If the treated exhaust air from any of these cabinets is discharged to the outside through the facility exhaust air system, it is connected to this system in a manner that avoids any interference with the air balance of the cabinets or the facility exhaust air system.

14. A specially designed suit area may be provided in the facility. Personnel who enter this area wear a one-piece positive-pressure suit that is ventilated by a life support system. The life support system is provided with alarms and emergency backup breathing air tanks. Entry to this area is through an airlock fitted with airtight doors. A chemical shower is provided to decontaminate the surface of the suit before the worker leaves the area. The exhaust air from the suit area is filtered by two sets of HEPA filters installed in series. A duplicate filtration unit and exhaust fan are provided. An automatically starting emergency power source is provided. The air pressure within the suit area is lower than that of any adjacent area. Emergency lighting and communication systems are provided. All penetrations into the inner shell of the suit area are sealed. A double-doored autoclave is provided for decontaminating waste materials to be removed from the suit area.

1.0 Introduction

Ergonomics is the science that addresses workers' performance and well-being in relation to their job tasks, tools, equipment, and work environment. It is a complex science that has its basis in several fields of research. Ergonomics analyses and solutions consider input from the following sciences and disciplines:

- Biomechanics
- Psychology
- Physiology
- Engineering
- Anthropometry
- Kinesiology

The application of ergonomics to the workplace is necessary for the following reasons:

- A more diverse workforce means that workplace design and job demands must reflect a wider range of worker capabilities and limitations (e.g., body size, strength, etc.).

- Ergonomics provides a means of accomplishing the goals of total quality and continuous improvement programs. Some facilities use ergonomic analyses to determine the effect of quality.

- There has been an increase in the reporting of cumulative trauma disorders related to insufficient implementation of ergonomic practices in the workplace.

- Regulatory activity has increased pertaining to ergonomics. Employers have been cited by the U.S. Occupational Safety and Health Administration (OSHA) under the general duty clause for failure to address ergonomics hazards.

This chapter describes measures that can be used to reduce exposure to, and in some cases remove, ergonomic stressors from the workplace. The measures that are presented include guidelines, worksite analysis, hazard prevention and control, medical management, and training. Although each EPA laboratory does not have its own ergonomist, many of the core elements of an ergonomics program (e.g., worksite analysis, hazard prevention and control) are already found in the laboratory safety programs. Thus, many tasks can be completed, only enlisting the aid of an ergonomist on an as-needed basis.

EPA Program Requirements

Each laboratory must:

- Conduct workplace assessments to identify ergonomic risk factors.
- Establish hazard prevention and control procedures.
- Ensure that employees have ergonomics training.

Program Administration

To ensure that ergonomics is effectively implemented, a local ergonomics committee f "human variation" on product (LEC) should be established that will be responsible for the programs' administration and maintenance. Appropriate members may include representatives from the following departments: facilities; Safety, Health, and Environmental Management (SHEM); and

occupational medicine. Once established, this group should distribute responsibilities for:

- Obtaining funding and staff support from upper management
- Measuring short- and long-term success
- Analyzing past OSHA 200 Logs and medical and safety records
- Developing tools to be used for worksite analysis
- Training employees on fundamentals of ergonomics

2.0 Work-Related Musculoskeletal Disorders

EPA laboratory employees are exposed to a variety of ergonomic stressors during the performance of their work tasks. Continual exposure to these stressors can result in a work-related musculoskeletal disorder (WMSD). Potential WMSD-type injuries common in laboratory environments include:

- Tendonitis
- Tenosynovitis
- Thoracic outlet syndrome
- Carpal tunnel syndrome

A WMSD is defined as:

> *Bodily injury secondary to mechanical stresses that results in a physical condition that has developed as a result of repeated stress on a particular body part.*

WMSDs develop due to an accumulation of stress or damage to the body over time. The body has great recuperative powers if given the opportunity to repair itself. However, when recovery time is insufficient and when repeated movements are combined with forceful and awkward postures, there is an increased risk that the damage will lead to injury.

Common characteristics associated with WMSDs may include pain, limited motion, soft-tissue swelling, possible diminished sensation, and the potential for lasting damage. Although these injuries require time to develop, their overall cost-related impact on the employee's health and the laboratory can be staggering. According to National Institute of Occupational Safety and Health (NIOSH), the cost to employers is more than 13 billion dollars annually, and more than 20 billion dollars annually according to the American Federation of Labor—Congress of Industrial Organizations. Figure C8-1 shows this injury cost to business.

The prevalence of ergonomics-related injuries and illnesses continues to increase. A 1997 Bureau of Labor Statistics study of more than two million cases that occurred in 1995 reported the following:

- One in four cases of back injuries or illnesses resulted in three to five days away from work.
- One in two cases of carpal tunnel syndrome results in 31 or more days away from work.

In addition, 25 percent of all lost workday cases and 30 percent of all workers' compensation costs were WMSD-related. Figure C8-2 shows the occurrence of WMSDs over time.

3.0 Ergonomics Guidelines

Although a regulation regarding ergonomics implementation does not exist, there are several regulatory groups that have either defined key program elements or have offered direction. The following sections summarize each group's activities pertaining to ergonomics.

3.1 OSHA

In 1997, OSHA drafted the "Ergonomic Program Management Recommendations" for general industry. Its purpose was to assist employers in preventing disorders

Figure C8-1: Injury Cost to Business

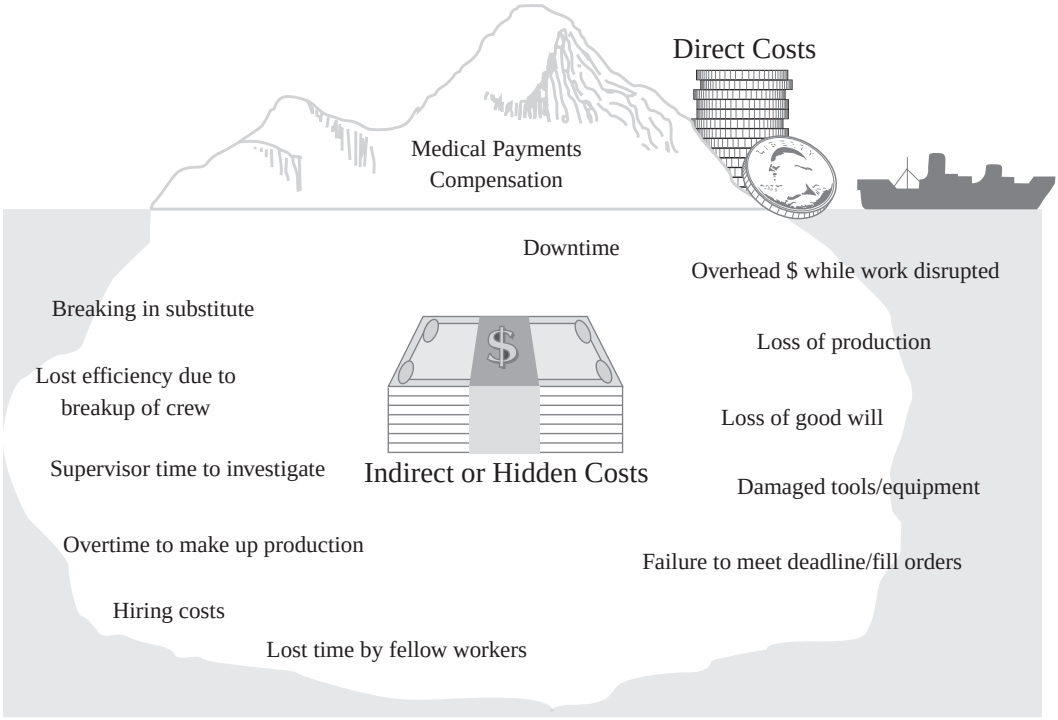
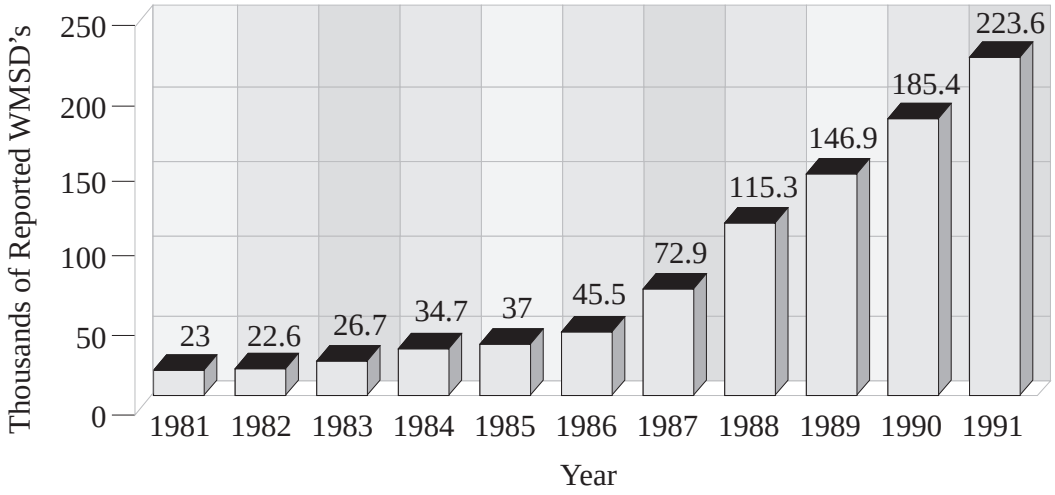


Figure C8-2: WMSD Occurrence



related to the lack of ergonomics in the workplace. This, as well as the standards described in the following section, is being used as the basis for a regulatory standard.

The regulatory standard may require employers to address ergonomic hazards by designing their ergonomics programs to include the items listed in Figure C8-3.

3.2 ANSI Standards

In 1988, the American National Standard Institute (ANSI) published a standard for "Human Factors Engineering of Visual Display Terminal Workstations," ANSI/ HFS 100. This voluntary standard is being updated to include guidelines for the following elements:

- Output devices
- Input devices
- Workstation fixtures
- Environmental considerations

The ANSI standard identifies several elements that should be included in an ergonomics program:

- Health- and risk-factor surveillance
- Job analysis and improvement
- Medical management
- Training
- Program evaluation

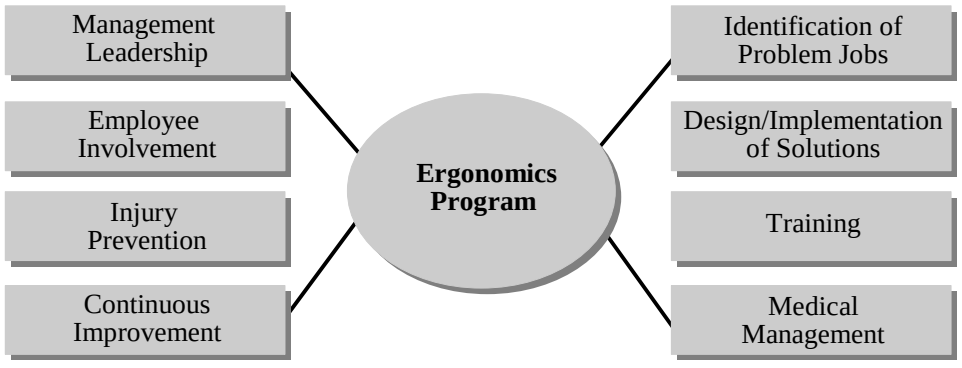
In addition, the ANSI Z-365 "Standard Control of CTDs," specifies principles and practices for the control of cumulative trauma disorders in the industrial workplace.

3.3 The Americans with Disabilities Act—Title I

Title I of the Americans with Disabilities Act (ADA) protects qualified individuals with disabilities from employment discrimination. Private employers, state and local governments, employment agencies, labor unions, and the joint labor-management committees must comply with Title I of the ADA.

Although the ADA is an extensive legal document requiring employers to set up policies that comply with the Act, the relationship between ergonomics and the ADA falls into three major categories:

Figure C8-3: Ergonomics Program



- Developing job descriptions that define the essential and marginal requirements of a job
- Providing reasonable accommodations for qualified workers with disabilities
- Identifying and addressing issues related to accessibility within the workplace

3.4 European Directive on Manual Handling

A directive on manual handling came into effect in Europe on January 1, 1993. The directive is a mandatory standard that applies to any manual handling operations that may cause injury at work. It requires employers to take at least three steps in reducing hazards:

- Avoid hazardous manual handling operations where reasonable.
- Assess any hazardous operation that cannot be avoided.
- Reduce the risk of injury as much as reasonable.

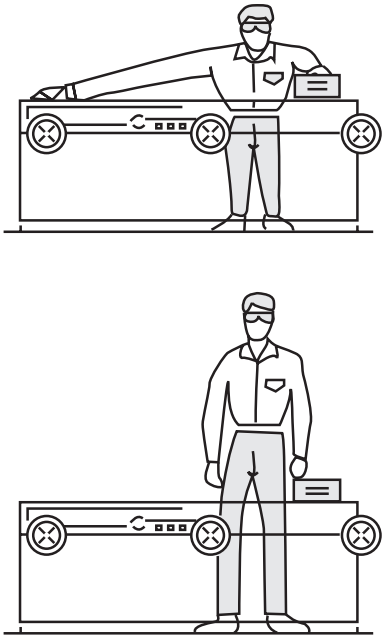
4.0 Human Capabilities and Limitations

When implementing ergonomics in any organization, there needs to be an understanding of essential guidelines for use when addressing human capabilities and limitations. The guidelines in the following sections should be considered when designing for human interactions.

4.1 Anthropometry

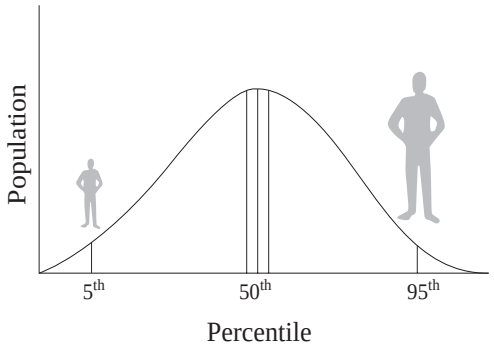
When designing for human beings, it is important to know their dimensions. Anthropometric data help to determine these dimensions. Anthropometry is the analysis of dimensions and proportions of the human body in relation to workstation design, equipment, furniture, and tools. Figure C8-4 shows a workstation not designed to account for workers of various sizes. Such a poorly designed workstation can result in awkward reaching and bending movements.

Figure C8-4: Human Proportions in Relation to Workstation Design



If a workstation is designed for the average person (e.g., the 50th percentile), only a small percentage of the population is accommodated. As such, workstations should be designed for 90 percent of the population, since the “average” person does not exist. Figure C8-5 shows the distribution of the majority of the population.

Figure C8-5: Distribution of the Majority of the Population



4.2 Occupational Biomechanics

In the design or evaluation of safe, efficient, and productive workplaces the interaction between workers and their tools, machines, and materials should be optimized. This will enhance the workers' performance while minimizing the risk of repetitive strain injuries.

Occupational biomechanics is the science that investigates and describes movement of the body segments (e.g., fingers, hands, arms, back) and the forces acting on those segments because of work being performed. The interaction of lever systems and torque in occupational biomechanics is presented in the following sections.

4.2.1 Lever Systems

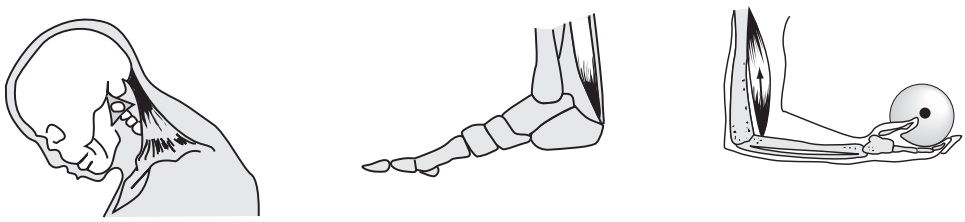
The muscles and bones that make up the musculoskeletal system function as a system of levers to accomplish tasks such as holding a tool, assembling, and lifting. Figure C8-6 presents examples of three classes of lever systems.

4.2.2 Torque

Torque is the rotation caused by the application of a perpendicular force at some distance from its axis. To counteract this rotation, the muscles react and create opposing forces. The resultant torques generated cause the muscles to contract and enable the human being to do mechanical work.

When a muscle's force is inadequate to counteract movement created by a load, the object falls. When a muscle's force is equal to the movement created by a load

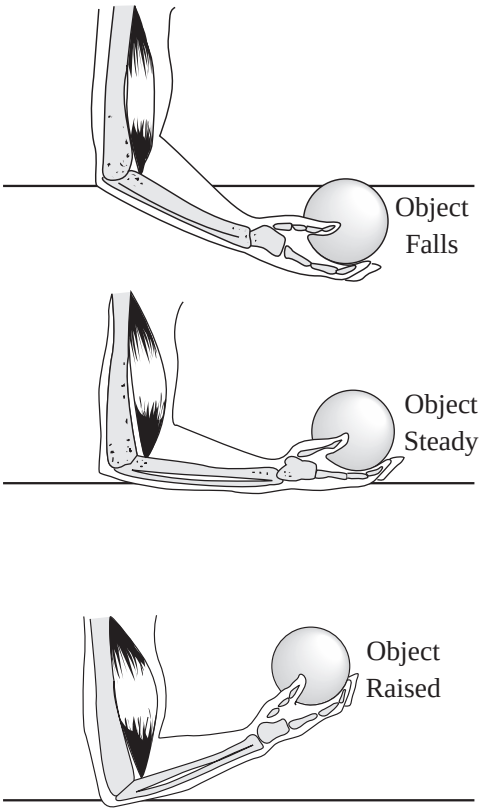
Figure C8-6: Classes of Lever Systems



in the hand, the object is held steady. When a muscle's force is greater than the movement created by a load in the hand, the object is raised.

Figure C8-7 shows three examples of the effect torque has on muscular contraction.

Figure C8-7: Effect of Torque on Muscular Contraction



5.0 Relevance to Job and Workplace Design

The goal of occupational biomechanics in job design is to minimize the reactive force that muscles must exert to counteract movement by controlling the weight load and distance.

Figure C8-8 demonstrates three lifting techniques, and indicates the total forward-bending moments on the lumbar spine, with the variations in resistance lever arms for the load (L_p) and the upper body mass (L_w).

Moving the object closer to the body's center of gravity reduces the forward-bending moment and results in less stress on the back and shoulder muscles.

Position (a) in Figure C8-8 is analogous to the low lifting of sheet material. Position (b) is similar to lifting over a vertical obstruction. Position (c) shows the recommended posture for lifting, but it assumes that the load can fit between the legs during the lift, which often is not possible.

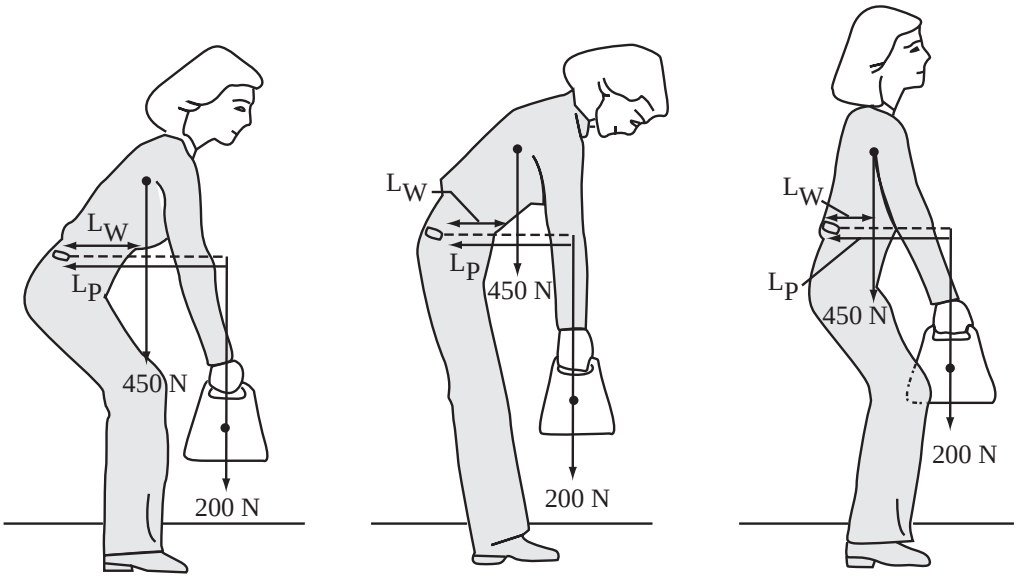
While worker training in lifting techniques can be beneficial, often the most effective approach is to promote recommended lifting positions through workplace and job design.

6.0 Worksite Analysis

Worksite analysis is a systematic method to control work-related injuries and illnesses and prevent future occurrences. Analysis tools used in the process will allow:

- Identification of "problem" jobs
- Determination of the risk associated with those jobs
- Initiation of problem-solving efforts

Figure C8-8: Lifting Techniques



(a) Total Forward-Bending Moment = 212 Nm

(b) Total Forward-Bending Moment = 192 Nm

(c) Total Forward-Bending Moment = 151 Nm

*N=Newton
*Nm=Newton-meter

This process will also provide baseline documentation on each job or job category in the laboratory. This can then be used to measure the results of ergonomics implementation on a case-by-case basis or to conduct department audits. The worksite analysis contains four steps as shown in Figure C8-9, each of which is discussed in the following sections.

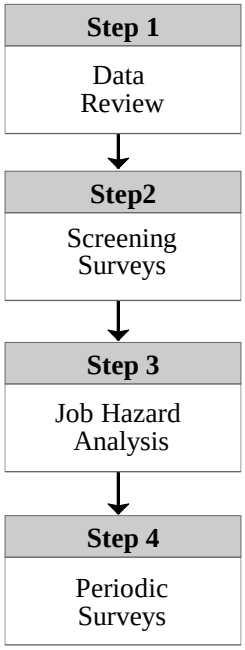
6.1 Step 1: Data Review

The first step is to review injury data. This review should result in a detailed summary of past and current reported injury experiences. The most accurate sources of injury data include the OSHA 200 Log and medical and safety records.

Employees can provide accurate information, usually in the form of complaints of discomfort associated with certain jobs. Every complaint should be recorded and followed up on to identify ergonomics concerns before a more serious condition develops. A sample employee complaint log is provided in Attachment C8-1.

This step represents a “reactive” but critical part of the overall worksite analysis process.

Figure C8-9: Steps in Worksite Analysis



6.2 Step 2: Screening Surveys

Screening surveys are an important part of the worksite analysis process. Although the depth of analysis found in a screening survey is less than a detailed job hazard analysis, the results can be used when targeting certain areas of the body (e.g., hands/wrists, back, shoulder, etc.).

There are many types of screening surveys available (e.g., objective scales, checklists, etc.). One appropriate means for targeting body area discomfort involves the use of a "body map," where specific body areas can be circled or shaded and the level of discomfort or pain can be identified. A sample "body map" is provided in Attachment C8-2.

This step also represents a "reactive" approach because it can quickly identify the presence of pain or discomfort. When combined with the results of the data review, the severity and magnitude of exposure to ergonomic stressors can be identified.

6.3 Step 3: Ergonomic Job Hazard Analysis

Ergonomic job hazard analysis (JHA) is a crucial step for determining stressor presence (e.g., sharp edges, large force projection, small handles) and level of exposure (e.g., high, medium, low).

Many times, the ergonomic JHA can be completed by using a checklist or other easily completed form. Although there are many factors that cause WMSDs, it is essential to emphasize those that occur for longer duration or those that are performed for a large portion of the task cycle. One example of a JHA checklist is provided in Attachment C8-3.

6.4 Step 4: Periodic Surveys

Periodic surveys are used to determine the success of ergonomics implementation. Although decreases in severity and incidence rates may occur as a result of implementation, the correlation to ergonomics implementation can be hard to justify. A more accurate survey would include the resultant risk as well as any decreases in worker discomfort or pain. Further periodic surveys could include employee early reporting and job satisfaction, and decreases in absenteeism and turnover.

7.0 Hazard Prevention and Control

Once hazards have been identified, the use of controls can aid in their reduction.

Engineering controls require a physical change to the work environment through equipment adjustment or purchase.

Administrative controls often require changes in work policy, such as increases in staffing or job rotation.

Work practice controls are used to identify the "best practices" to employ when performing a task (e.g., instruction in the correct lifting technique).

The following sections discuss the use of engineering controls in designing workstations and tools.

7.1 Workstation Design

For laboratory environments, correctly designed workstations can reduce exposure to ergonomic stressors. When designing workstations, perform the following:

- Design the height of the point of operation to allow neutral shoulder and wrist positions.
- Provide a height-adjustable workstation.
- Provide soft, padded armrests to minimize static stress and external trauma.
- Provide arm supports when the visual distance or control location requires the point of operation to be above seated elbow height.
- Place controls or materials within reach; avoid placement to the sides, behind, and/or above shoulder height.
- Provide space for objects or materials to be located 16 to 18 inches in front of the body and between the elbows and shoulders.
- Provide clear knee space for seated workers, and foot rails for standing workers.
- Provide adequate lighting for detailed tasks (e.g., 75 foot-candles).
- Provide adjustable seating to accommodate workers ranging from 4 feet 8 inches tall and 97 pounds to 6 feet 2 inches tall and 217 pounds.

7.2 Tool Design

The tools used in EPA laboratories can range from microscopes and pipettes to tweezers and other small hand tools. Although these tools can differ in their function, it is important that they contain the following features:

- Focusing knobs on the microscope should have large diameters and require small manipulation forces.
- Eyepieces and necks on the microscope should be adjustable in tilt, horizontal, and vertical position.
- Joysticks used to manipulate optical viewing devices (e.g., cameras) should have a built-in hand-resting surface.
- The gripping surfaces on tweezers and the barrels on small hand tools should be compressible and of a sufficiently large size (i.e., greater than one inch).

- Triggers on multi-channel pipettes must allow for at least two fingers and should not activate by using thumb pressure.

- Handles on small tools should not press into the palm or have grooves and sharp edges.

7.3 Design of Work Practice Controls

Although engineering controls are the most effective in eliminating risk factor exposure, at times they are not justifiable for economic or practical reasons. When this is the case, carefully designed work practice controls can aid in risk factor reduction.

The major components of work practice controls include work procedures and job design. The following guidelines should be followed when designing work practice controls:

- Involve all affected employees.

- Train employees in fundamental ergonomic principles. This will be the basis for deciding how to perform each element of a task with a minimum risk to employees.

- Divide the job into subtasks and identify the best method for performing each subtask based on ergonomic principles.

- Create a simple written procedure that includes photographs describing each major subtask.

- Use written work procedures when training new or transferred employees.

8.0 Medical Surveillance

An effective medical surveillance program for WMSDs is essential to the success of an ergonomics program. The program should identify the elements that will ensure early evaluation, diagnosis, and treatment of WMSDs, as well as implementation of preventive measures. For more information on medical surveillance requirements, refer to Chapter C2 of this manual.

8.1 Appropriate Personnel

A certified occupational health nurse or occupational medicine physician with appropriate training should be involved in the development and administration of the medical surveillance process. Each EPA laboratory should have access to health care providers to facilitate treatment, supervise activities, and record information. Their findings should be a topic of discussion during safety meetings.

8.2 Components of a Medical Surveillance Program

The following are the components of a medical surveillance program designed for the prevention and treatment of WMSDs.

8.2.1 Workplace Walkthrough

To identify potential restricted-duty tasks and to maintain contact with employees Medical surveillance personnel and SHEMP Managers should remain knowledgeable about current operations and work practices. This element is essential

as it demonstrates laboratory management's commitment to employee well-being.

8.2.2 System Surveys

This method of worksite analysis is used to determine the existence of ergonomic problems in the facility, and establish a baseline for further comparison. Survey forms should identify the location, duration, and severity of the discomfort. This can be facilitated quite easily with body diagrams. Employee participation can be encouraged by eliminating potential worker identifiers (e.g., name, SSN, etc.).

In order for a WMSD to heal, the employee should be placed in a work environment in which the muscle-tendon unit will have time to rest. For this to occur, the current task and new tasks being considered should be examined to determine the risk to the structures involved (e.g., shoulder tendon).

8.2.3 Early Reporting of Symptoms

Early reporting of potential WMSDs will allow for timely and appropriate evaluation and treatment without fear of discrimination or reprisal. It is vital that any potential disincentives for employee reporting (e.g., limits on the number of times an employee may visit the health unit) are eliminated.

8.2.4 Appropriate Medical Care

Once a WMSD has been identified, it is essential for there to be established protocols for dealing with evaluation (e.g., diagnostic tools), treatment (e.g., anti-inflammatory medication and exercise), and follow-up assessment.

9.0 Employee Information and Training

Although an effective ergonomics program can help detect and prevent WMSDs through symptom surveys and periodic walk-throughs, ergonomics training is vital for recognizing current problems and for creating a forum for discussing employee concerns. Refer to Chapter C3 of this manual for more information on ergonomics training.

10.0 Material Handling Techniques

Material handling has historically led to many musculoskeletal injuries. By implementing guidelines for material handling, injuries may be drastically reduced.

10.1 Pushing/Pulling

Basic guidelines for pushing and pulling include the following:

- Use two hands instead of one.
- Push at waist level instead of at shoulder or knee level.
- Pull at knee level instead of at waist or shoulder level.
- Keep machines and equipment well maintained and lubricated to ease pushing and pulling.
- Avoid ramps, long distances, and high repetition.

10.2 Holding

There are some situations in which the worker holds the object without any movement, creating a static load. Employees should use proper posture

and tipping aids to reduce strain caused by holding objects. Basic guidelines include the following:

- Avoid holding objects above shoulder height and away from the body (especially to the sides).
- Use tipping aids to counterbalance drums when pouring.

10.3 Carrying

There are many different ways to carry objects, each associated with different stresses and strains. Methods for carrying objects should be appropriate for the specific task performed.

10.3.1 Carrying With the Back and Shoulders

Guidelines for carrying with the back and shoulders include the following:

- Keep the load close to the body.
- Carry light loads often instead of large loads occasionally.
- Use mechanical assistance where possible.

10.3.2 Hand Carrying

During hand carrying, employees should avoid twisting, bending, and excessive loads all of which may stress the back. The use of mechanical aids to move objects should be encouraged. Appropriate postures, such as using the proper wrist position, are important in reducing stress as well.

10.4 Lifting

Proper lifting techniques should be part of an overall program of hazard prevention and control that focuses on eliminating the source of potential ergonomic problems through engineering change. Many guidelines that often include complex calculations may be used for lifting analysis, but employees should focus on the following basic guidelines:

- Bend at the knees instead of at the waist.
- Lift the load slowly.
- Pivot or move feet instead of twisting at the waist.
- Use materials handling equipment whenever possible.
- Make more trips with less weight.
- Maintain a good grip on the object by using as many fingers as possible.
- Keep the load close to the body.
- Lift and carry items between the waist and shoulders.
- Ask for assistance when carrying large or bulky loads.

11.0 Work Postures

To reduce the occurrence of WMSDs, employees should use appropriate work postures. The following guidelines should be implemented:

- Avoid awkward positions for extended periods of time (e.g., arms away from the side or behind the body, wrists bent).

- Set the work height at two inches below the elbow.

- Adjust chair control levels to obtain correct heights.

Attachment C8-1: Employee Complaint Log

Purpose: To provide an example of an employee complaint log form.

Instructions: Use this form to record employee complaints related to ergonomic stressors.

Employee Complaint Log

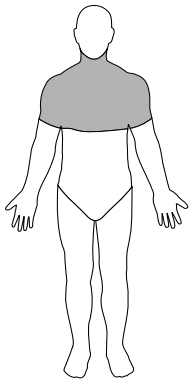
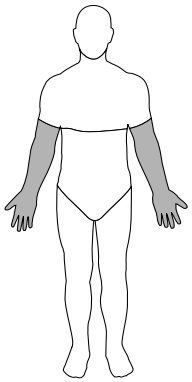
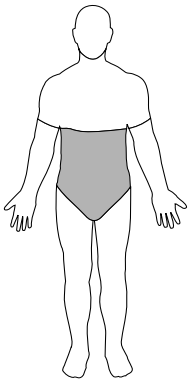
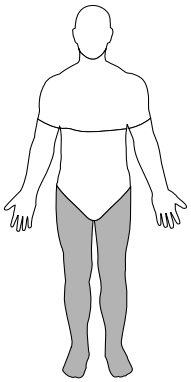
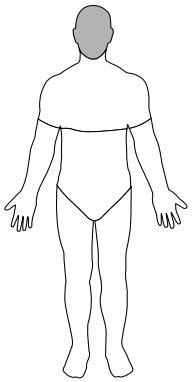
Complaint Date	Employee Name	Job/ Task	Dept.	Body Area	Injury Type, Severity, Duration	Follow-up Action	Follow-up Date

Attachment C8-2: Body Map

Purpose: To provide an example of a form that can be used to map locations of ergonomic stressors on the body.

Instructions: Use this form to identify how the body responds to the demands of a job task. In each section, answer the first question. If the answer is "No," go to the next column.

Body Map: Response to Work Demands

Question	Shoulder/Neck	Hands/Wrists/Arms	Back/Torso	Legs/Feet	Head/Eyes
					
• In the past 12 months, have you experienced *any* discomfort, fatigue, numbness, or pain that ***relates to your job?***	1. Yes ❑ No ❑ ***If "No," go to Question 4***	4. Yes ❑ No ❑ ***If "No," go to Question 7***	7. Yes ❑ No ❑ ***If "No," go to Question 10***	10. Yes ❑ No ❑ ***If "No," go to Question 13***	13. Yes ❑ No ❑
• How often do you experience discomfort, fatigue, numbness, or pain in this region of the body?	2. Daily ❑ Weekly ❑ Monthly ❑	5. Daily ❑ Weekly ❑ Monthly ❑	8. Daily ❑ Weekly ❑ Monthly ❑	11. Daily ❑ Weekly ❑ Monthly ❑	14. Daily ❑ Weekly ❑ Monthly ❑
• On average, how severe is the discomfort, fatigue, numbness, or pain in this region of the body?	3. Mild ❑ Moderate ❑ Severe ❑	6. Mild ❑ Moderate ❑ Severe ❑	9. Mild ❑ Moderate ❑ Severe ❑	12. Mild ❑ Moderate ❑ Severe ❑	15. Mild ❑ Moderate ❑ Severe ❑

Attachment C8-3: Ergonomics Checklist

Purpose: To provide an example of an ergonomics checklist.

Instructions: Use this checklist when analyzing a job task for risk factors.

Ergonomics Checklist

Risk Factors		X<10%	10–50%	50%>X	Solution Opportunities Group
		0	2	3	
Force					
1	Does the hand or wrist rest on sharp edges?				Attach a compressible surface to the workstation edge.
2	Is an object continually held in one hand?				Provide a holding device or clamp.
3	Does the task require projecting more than 8 pounds of repeated fingertip force?				Increase the object's surface area to allow for a larger contact area.
4	Is the worker subjected to tool or surface vibration?				Provide antivibration gloves or tool wraps, and attach compressible surfaces to workstation edges.
5	Is the tool activated by a single-finger trigger?				Adapt trigger for multiple fingers.
6	Are objects heavier than 52 pounds manually lifted?				Use materials handling equipment or alternative material delivery methods for heavy objects.
7	Does materials handling require lifting and holding or careful placement or alignment?				Consider providing transfer devices or carts to hold, place, or control objects.
8	Does the object have to be carried for more than five steps?				Provide a cart or hoist, or move the start and end locations closer together.
9	Does object movement require lifting from the floor to above the shoulder height?				Place frequently lifted objects at least 20 inches off the floor and lift objects no higher than 60 inches.
10	Is the cart hard to push because of poor wheels or bearings?				Ensure that wheels and bearings are rated for the load capacity.
11	Is cart control inhibited by handle size, shape, or location?				Use tubular handles that are 1.5 to 1.8 inches in diameter and are 41 inches from the ground.
Force Total					

Ergonomics Checklist (continued)

Risk Factors		X<10%	10–50%	50%>X	Solution Opportunities Group
		0	2	3	
Position					
1	Are awkward body positions repeatedly held for more than 10 seconds during the task?				Raise or lower the object so that a neutral body position is possible.
2	Does the object movement require forward or sideways bending and/or twisting of more than 15°?				Raise the object so that it is higher than 20 inches and place the start/end locations next to each other.
3	Does the employee have to repeatedly reach above shoulder height or behind the body to get parts or supplies?				Place objects or items below the individual's shoulder height and in front of the body.
4	Are the elbows positioned comfortably at the sides?				Place the object so that the elbows are positioned comfortably at the sides; provide upper-limb supportive devices (e.g., padded work surfaces, arm rests).
5	Are the cart's contents placed lower than 19 inches?				Provide carts with higher shelves; place light objects on lower shelves.
6	Does the task require unsupported holding of tools weighing more than five pounds?				Provide supportive surfaces for the upper limb or the tool.
7	Do tool handles for precision tasks have compressible surfaces?				Attach compressible surfaces so that the barrel diameter is at least 1.5 inches.
8	Does the tool handle design or its use require awkward upper limb positions?				Modify the tool handle to allow for proper orientation, or reposition objects to allow for more neutral positioning.
9	Does the tool handle have sharp edges?				Attach compressible surfaces to the handle or provide gloves.
Position Total					

Ergonomics Checklist (continued)

Risk Factors		X<10%	10–50%	50%>X	Solution Opportunities Group
		0	2	3	
Frequency					
1	Are the worker's hands exposed to cold temperatures?				Provide gloves or redirect exhaust away from hands.
2	Are similar wrist, elbow, or shoulder motions repeated every task cycle?				Provide job variety or rotation opportunities to allow for rest.
Frequency Total					

Risk Factors	Totals
Force	
Position	
Frequency	
Overall Task Subtotal	

Overall Task	÷	Total Possible Score	x	100	=	Overall Risk

1.0 Introduction

The EPA defines pollution prevention (P2) as source reduction and other practices that reduce or eliminate the creation of pollutants through increased efficiency in the use of raw materials, energy, water or other resources, and protection of natural resources by conservation. The following Executive Orders drive current federal facility requirements for P2:

Order 12856: "Federal Compliance with Right-to-Know Laws and Pollution Prevention"

Order 12873: "Federal Acquisition, Recycling, and Waste Prevention"

Order 12902: "Energy Efficiency and Water Conservation"

One of EPA's goals is to ensure that P2 becomes part of the environmental ethic at every level of the federal government; a related goal is that federal workers integrate environmental considerations into their work.

EPA Program Requirements

To assist the integration of P2 techniques as set forth in the Agency's Code of Environmental Principles (CEMP), EPA laboratories must:

- Develop a P2 plan.
- Apply source reduction to facility management and to acquisition practices.
- Establish a voluntary goal to reduce total releases and off-site transfers of toxic chemicals and pollutants.
- Establish a plan to reduce or eliminate the acquisition and procurement of products containing extremely hazardous substances or toxic chemicals.

To apply energy conservation, EPA laboratories must:

- Develop a program to reduce energy consumption.
- Develop a program to increase energy efficiency.
- Develop a program to reduce petroleum use.
- Conduct surveys and audits based on facility priorities in energy conservation.
- Meet facility construction and leasing requirements.

Program Administration

P2 opportunities exist in all aspects of laboratory management. To effectively manage a P2 program, responsibilities should be assigned for:

- Identifying sources and amounts of laboratory pollutants
- Targeting process or material changes that will result in pollution reduction
- Determining the potential for cost savings related to specific pollution reduction techniques
- Evaluating the effectiveness of the P2 program annually

To effectively manage energy conservation at EPA laboratories, responsibilities should be assigned for:

- Defining laboratory goals for energy conservation

- Identifying high-priority areas for improving energy consumption
- Organizing energy teams
- Providing incentives for energy conservation
- Measuring effectiveness of energy-conservation techniques

2.0 P2 Program

Executive Order 12856 requires the federal government to apply source reduction to the management of its facilities. The Order requires each federal agency, including the EPA, to:

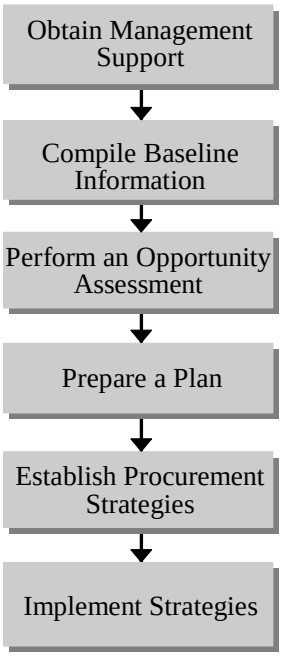
- Develop a written P2 strategy and policy statement emphasizing source reduction as the primary method of environmental protection.
- Submit Toxic Release Inventory (TRI) reports for all releases or transfers of toxic chemicals for all agency facilities that exceed thresholds for manufacture, use, or processing of toxic chemicals, as defined under the Emergency Planning and Community Right-to-Know Act (EPCRA) Section 313, without regard to Standard Industry Code (SIC) limitations.
- Comply with the emergency planning and response provision under EPCRA Sections 302 and 312.
- Develop voluntary goals to reduce total releases and off-site transfers of TRI chemicals by 50 percent by 1999.
- Establish a plan and goals for eliminating or reducing the unnecessary procurement of products containing extremely hazardous substances or toxic chemicals.
- Revise specifications and standards, and identify opportunities, to eliminate or reduce procurement of extremely hazardous substances or toxic chemicals.

The EPA also requires that each covered facility develop their own P2 program. This program must include a plan that sets forth the laboratory's contribution to the agency-wide 50-percent reduction goal.

A successful P2 program involves:
- Calculating a P2 baseline
- Conducting an opportunity assessment
- Preparing a P2 Plan
- Developing a procurement strategy
- Implementing P2 initiatives

The following sections, and Figure C9-1, outline a methodology for EPA laboratories to develop a successful P2 program.

Figure C9-1: Development of a P2 Program



2.1 Obtain Management Support

The EPA is committed to fulfilling both the spirit and letter of Executive Order 12856. Therefore, laboratory Safety, Health, and

Environmental Management Program (SHEMP) managers should document their commitment of resources to properly implement a P2 program. This includes designating roles and responsibilities throughout the laboratory, appointing a P2 coordinator to serve as a focal point for program implementation, and communicating the importance of P2 to employees.

2.2 Compile Baseline Information

To properly develop a P2 program, laboratories must identify and compile baseline information on material usage, release profiles, and environmental impacts related to laboratory operations. Hazardous chemicals, waste streams, and water and energy consumption should all be quantified to the fullest extent possible. Major laboratory processes should be diagrammed and mass balances of pollutants developed. Such an accounting allows laboratories to prioritize the emphasis of their P2 strategy.

The P2 Coordinator must develop a consistent method for documenting information and may need to organize a team to collect the necessary data. Information necessary for developing a baseline includes:

- Quantities of chemicals used and disposed of
- Raw material costs
- Disposal costs
- Procurement practices
- Process requirements

Most of this information can be gathered by reviewing purchasing records, inventory quantities, disposal and transfer data, and on-site treatment data. Interviews with people from various organizations or specialty areas will also help the coordinator or team members understand the specific practices occurring in the laboratory.

2.3 Perform an Opportunity Assessment

A P2 opportunity assessment is a systematic analysis that identifies operational characteristics that create environmental impacts, such as waste generation, toxic chemical releases, power and water consumption, and ecosystem damage. The overall goal of the assessment is to identify which laboratory processes and operations are best suited for P2 projects. Assessments therefore should target the processes and materials having the highest probability of yielding significant reductions in pollution. Some facilities form teams consisting of operations, maintenance, environmental, and engineering personnel to identify the most promising P2 opportunities.

During the data collection phase of the assessment, the team must be careful to ensure that information is gathered in a consistent and accurate manner, possibly through the use of a uniform data collection worksheet.

Interviews should be conducted with personnel involved in each process to understand the operability of the process and whether any improvements to the process can be implemented to accomplish pollution reduction. Information for each process should include the following:

- A characterization of all aspects of the process or operation, including process flow, waste generation patterns,

material and energy consumption, costs, manpower, and reliance on toxic chemicals

- Impacts that the process and related wastes have on the air, water, and land
- Associated impacts and wastes with specific unit operations
- Related costs and liabilities of specific waste streams
- Cost-effective technical and procedural options that will minimize waste and pollution

Once each process is defined, the assessment team should meet to discuss the results. The purpose of this meeting should be to identify possible P2 projects and to target areas requiring further investigation. For each potential project, the degree of pollution reduction, cost, and process performance should be documented to aid the decision process. Relevant factors to consider when evaluating a project include:

- The impact of the project on regulatory compliance
- How the project effects critical turnaround times and quality
- The actual reduction of pollutants the project will achieve
- What resources will be required to implement the project
- The economic implications of this project

P2 projects that use source reduction concepts (e.g., raw material substitutions, inventory control, equipment modifications, and process changes) should be the laboratory's top priority for implementation where possible.

EPA facilities have numerous P2 projects in progress. Many of these projects represent innovative approaches to P2. A sample of these projects is provided in Attachment C9-1.

2.4 Prepare a P2 Plan

Executive Order 12856 requires all covered facilities to develop and implement written P2 plans to ensure that the quantity of toxic chemicals released into the environment is reduced as quickly and efficiently as possible through source reduction, recycling, etc. Each facility needs to develop a plan to set goals and targets for pollution reduction and P2 projects.

To maintain consistency across the Agency, EPA laboratories should create a plan that includes, at a minimum, the elements described below:

- ***Purpose:*** Outlining the specific goals of the laboratory and establishing a link with the overall goals of the Agency
- ***Mission:*** Describing the relationship of the program to the laboratory's overall mission
- ***Roles and Responsibilities:*** Defining the laboratory personnel's roles and responsibilities for fulfilling the objectives of the plan (the team coordinator should have responsibility for ensuring implementation of the plan)
- ***Baseline:*** Establishing parameters to be monitored

- ***Summary of Ongoing and Planned Initiatives:*** Identifying projects that will achieve the laboratory's goals

- ***Performance Metrics:*** Discussing the methodology the laboratory will use to track its progress against its goals

- ***Training:*** Addressing any training planned to educate facility personnel about P2 (this training may be awareness training, training at the operational level, or training for select groups)

The P2 plan represents the environmental road map for reducing waste generation, reducing worker exposure to hazardous materials, protecting natural resources, and minimizing environmental impacts caused by facility operations. It should be reviewed yearly and updated as necessary.

For further information on developing a P2 plan, consult EPA's Facility Management and Service Division (FMSD) Guidance Manual for developing P2 plans. Copies of all P2 plans completed by facilities are available from SHEMD.

2.5 Establish Procurement Strategies

Under Executive Order 12873, each federal agency must establish goals and a plan for eliminating or reducing the unnecessary acquisition of products containing extremely hazardous substances or toxic chemicals. This Executive Order recommends guidelines for federal agencies to follow when determining which environmentally-friendly substitutes to purchase.

Executive Order 12873 defines these "environmentally-preferable products and services" as those that "have a lesser or reduced effect on human health and the environment when compared with competing products and services that serve the same purpose." EPA laboratories should review purchasing and acquisition practices in order to maximize use of these products and, in turn, minimize the amount of waste generated by their operations.

Laboratories should also refer to the EPA's final Comprehensive Procurement Guideline (CPG) that designates 19 items for priority use, based on their recovered-material content. Laboratories should choose these materials whenever possible, and purchasing personnel should work with the P2 coordinator to order smaller amounts of chemicals.

Another successful component of procurement strategy is the chemical adoption program. Laboratories, facilities, or offices enter information describing partially used or excess products into a data-tracking system. The system then posts the available products in an accessible location or on a network. Organizations can access the system to request products in the necessary quantity instead of purchasing new materials. Several EPA laboratories even require written verification that the system was checked before any new chemicals are purchased. This system can significantly reduce the amounts of chemicals requiring disposal and it acts in tandem with a successful procurement strategy.

Although this system is primarily used by laboratories requisitioning chemicals, the process can be extended to include maintenance cleaning supplies, surplus furniture, or laboratory and office equipment.

2.6 Implement Strategies

After the laboratory calculates a baseline, conducts opportunity assessments, prepares a P2 plan, and develops procurement strategies, it must implement the P2 projects it has selected. By developing a strategy for program implementation, the laboratory's P2 coordinator can quickly integrate P2 activities into the laboratory's daily operations. Strategies may include technology transfer and employee training.

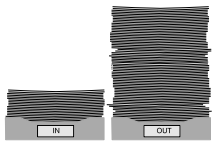
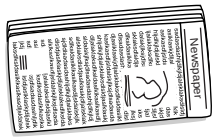
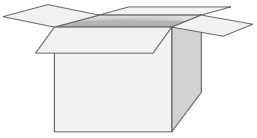
Technology transfer essentially involves borrowing implementation techniques from other laboratories and modifying them to fit the needs of the target facility. Information on similar programs can be attained from other EPA facilities through conferences, meetings, and training sessions. Placing requests for information sharing on bulletin boards or in newsletters is another way of sharing technology.

Another strategy for implementing P2 projects is through employee training. Laboratories can create specific P2 training courses or they can modify existing courses to include short segments on P2. Existing courses in hazardous waste minimization and hazard communication provide good forums for providing P2 information. Also, the EPA Learning Institute offers a P2 awareness course for all employees. The EPA SHEMD multimedia library also offers a module on P2. An adequately informed and trained workforce will more readily integrate P2 initiatives into daily operations at the laboratory.

3.0 Recycling

The Source Separation for Materials Recovery Guidelines found in 40 CFR Part 246 require federal facilities to implement recycling programs for high-grade paper, newspaper, and corrugated cardboard if they exceed the thresholds in Table C9-1.

Table C9-1: Thresholds for Implementing Recycling Programs

Material	Recycling Program Required if:
High-grade paper 	More than 100 office workers
Newspapers 	More than 500 families reside
Corrugated cardboard 	More than 10 tons per year generated

States have recently begun to require recycling programs for non-hazardous waste through such regulatory actions such as banning certain wastes from landfills. Regardless of regulation, federal facilities

are encouraged to establish recycling programs to reduce disposal costs.

In addition to encouraging collection of wastes for recycling, federal regulations require the procurement of goods made from recycled material, provided they are equivalent in quality and price to goods made from virgin stock. The categories of products containing recycled materials include building insulation products; cement and concrete that contains fly ash; lubricating oils that contain re-refined oil; paper and paper products; and retread tires.

In addition to the requirements identified in Table C9-2, other solid waste management regulations favor recycling over disposal by providing, in some cases, regulatory relief. For example, certain used-oil management techniques and some storage practices for used lead-acid batteries are exempt from hazardous waste regulations.

The following sections discuss the development and implementation of a recycling program.

3.1 Recycling Program

Factors critical in maximizing the efficiency of a recycling program include:

- Defining a program that maximizes recovery of recyclables and return on program investment
- Optimizing the collection strategy based on facility layout and targeted recyclables
- Selecting target recyclables based on economics and waste generation
- Communicating recycling results to stakeholders
- Evaluating recycling program performance and adjusting program attributes
- Marketing collected materials to offset program costs

Table C9-2: Recycling Regulations and Guidelines

Citation	Name
42 U.S.C 6901 et seq	Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act, as amended
EO 12873	Federal Acquisition, Recycling, and Waste Prevention
40 CFR 246	Guidelines for Source Separation for Materials Recovery
40 CFR 247	Guidelines for Procurement of Products That Contain Recycled Material

A commonly overlooked element of a successful recycling program is the recycling plan. A recycling plan should include the elements summarized in Figure C9-2 and discussed in the following sections.

3.1.1 Policy and Management Commitment

It is important to have a clear policy that is linked to the overall mission of the facility as well as to federal requirements pertaining to P2. Federal facilities have an advantage over commercial concerns in that there are a number of executive orders and department directives that emphasize recycling over disposal.

For example, Executive Order 12088 "P2 at Federal Facilities," requires agencies to prevent environmental pollution at their facilities. Executive Order 12873 "Federal Acquisition, Recycling, and Waste Prevention," broadens and strengthens the role of the federal government in the procurement of recycled and environmentally preferable products.

Figure C9-2: Elements of a Recycling Program

The commitment of laboratory management is necessary to demonstrate to all employees that the recycling program is a priority for the facility. Laboratory management commitment is typically demonstrated through approval of the recycling program plan as well as through involvement in the communication of the plan. For large facilities, integrating the laboratory management into an introductory training video is a good method of demonstrating commitment. For smaller facilities, periodic memoranda from senior management work well. One of the biggest demonstrations of commitment from laboratory management is allocation of resources. Adequate funding is crucial to prove to employees that a laboratory is serious about recycling.

3.1.2 Goals and Objectives

The recycling program should set goals and objectives that are easily evaluated. Numerical recycling goals can be difficult to evaluate if they are not expressed as a percentage of total materials recovered. One method of establishing numerical goals and objectives for recycling involves measuring performance against a baseline year. The problem with this approach is that changes to the laboratory's mission can dramatically affect the amount and type of solid waste generated, rendering any comparison to previous recycling performance a meaningless exercise.

It can be more effective to express goals and objectives in terms of more subjective accomplishments. Some examples include:

- Complying with federal, state, and local regulations and requirements

- Fostering a philosophy to conserve resources and minimize waste and pollution
- Reducing the amount of waste requiring disposal

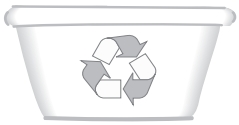
Some laboratories have increased the success of recycling programs by donating the proceeds from material sales to a local charity or employee activity fund. This approach, while not the most attractive from a revenue-generation standpoint, usually increases recovery of recyclables. It can also be effectively applied to selected materials in the solid waste stream. For example, proceeds from aluminum can sales could be donated to charity while proceeds from office paper recycling could be used to offset some costs of the recycling program.

3.1.3 Resources

Resources necessary to administer the recycling program include labor, equipment, and supplies. The recycling program plan should specify the program budget and means of accounting. Large facilities can establish discrete charge numbers for recycling to allow accurate tracking of resource use. Smaller facilities will need to determine a means to track labor so that the true cost of recycling can be calculated. A typical federal facility draws resources from its environmental or maintenance organization to operate an effective recycling program.

The most important equipment used in a recycling program are the containers that form the collection network. If the containers are convenient to use, then material recovery will increase. For example, an office paper recycling program with collection bins in every office will be more successful than one with a single bin in the corridor. However, this increased convenience also increases the cost of materials and labor.

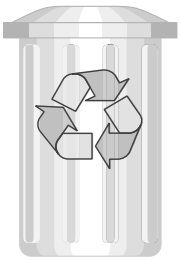
The material to be recycled dictates the design of the collection system. Office paper recycling is best accomplished with small bins in individual offices and larger bins near photocopy machines. Maintenance or janitorial personnel should periodically empty the bins into a larger container for ultimate transport to a central storage location (e.g., a dumpster).



Collection bins for aluminum cans and glass should be placed next to vending machines and in break areas.

Pallets and corrugated cardboard are generally stockpiled in dumpster-sized containers stationed near warehouses and shipping/receiving areas. Some large facilities use hydraulic compactors for these materials to conserve space.

For collection networks, durable bright-colored containers and labels are effective. Labels are particularly important for office paper programs due to the various grades of office paper that must be sorted (e.g., GBC-bound, stapled, and glued reports; glossy paper; color printing, etc.). For aluminum and glass containers, a plastic trash barrel with a hole cut in the center provides an adequate and inexpensive collection receptacle. Plastic reusable containers can be used for nickel-cadmium



batteries and toner cartridges.

3.1.4 Roles and Responsibilities

The plan must clearly define roles and responsibilities for administration and implementation of the recycling program. Roles and responsibilities should be defined for the Laboratory Director, program administrator, collection personnel, and all employees.

- The Laboratory Director should review and approve the recycling program plan; review program progress; commit and allocate the necessary resources to effectively implement the program; and assist with communicating and promoting awareness.

- The program administrator should develop and maintain the recycling program plan; implement the program as specified in the plan; identify program deficiencies and corrective actions; evaluate recycling program performance; and coordinate program communications.

- Laboratory management should ensure implementation of the recycling program in laboratories under their control.

- All employees should participate in the recycling program and work to identify opportunities to minimize the amount of waste requiring disposal.

3.1.5 Communication and Awareness

There are a number of ways to communicate progress on recycling and to promote participation and awareness. The conventional way of communicating recycling program progress is through regular features in newsletters or bulletin board postings. These features usually report the quantity of material recycled, the amount of money generated by the sale of recyclables, and comments on noteworthy aspects of the program. Some laboratories track the amount of waste recycled within each building and provide a small reward or recognition for the building with the highest recovery rate. Remember that the goal of the communication program is to increase recovery and sustain the recycling program. Therefore, it is important to portray these competitions in a way that does not discourage recycling.

3.1.6 Training

SHE training for all personnel should provide an introduction to the recycling program, thereby teaching a new employee about the program.

Staff with additional responsibilities for collecting and accumulating recyclables should be instructed on what materials should be removed from office paper recycling bins (e.g., colored paper) before dumping the bins into collection barrels or dumpsters. Typically this training can be integrated with existing training programs as discussed in Chapter C3 of this manual.

3.1.7 Program Evaluation and Oversight

This program element is important in fostering continuous improvement. The program administrator should track the types and amounts of materials recycled and maintain this information on a spreadsheet to allow analysis and presentation of the data. Quarterly progress reports are sent to laboratory management. Articles in

newsletters or posted on bulletin boards should also be issued quarterly. Useful statistics to present graphically include the amount of each material recycled and a total recycling rate for the current quarter, year to date, and a comparison to previous years.

In addition to quantifying recovery rates, it is important to obtain feedback from employees. The recycling program administrator should periodically survey selected individuals to identify possible areas for program improvement. Janitorial staff can often identify whether the collection system is effective in ensuring appropriate recyclable quality.

3.2 Procurement of Recycled Materials

The EPA has established requirements for procuring products containing recycled materials. EPA laboratories must require that vendors:

- Certify that the percentage of recovered materials to be used in performing the contract is at least the amount required by applicable specifications or other contractual requirement

- Estimate the percentage of recovered materials used for the performance of the contract

EPA laboratories are required to establish a program to purchase items containing recovered materials to the maximum extent practicable. The program must contain the following four elements:

- Preference programs for purchasing designated items

- Promotion program

- Procedures for obtaining estimates and certifications of recovered material content and for verifying the estimates and certifications

- Annual review and monitoring of the effectiveness of the program

Individual laboratories are encouraged to coordinate this effort with the EPA SHEM Division to promote consistency and sharing of lessons learned.

4.0 Energy Conservation

By investing in energy-efficient techniques to heat or cool a building, heat and circulate water, operate lights, run appliances, and run ventilation fans and motors, EPA laboratories can save both energy and money. Energy conservation requires a total-systems approach. The requirements for energy conservation at federal facilities (as well as guidelines for meeting these requirements) are set forth in Executive Order 12902.

4.1 Reduction Goals

By practicing energy conservation techniques, EPA laboratories can cut costs and assist the Agency in reaching its goals of reducing consumption. Reducing consumption can help achieve the following Agency goals as set forth in Executive Order 12902:

- Reduction of energy consumption by 30 percent by the year 2005

- Increase of energy efficiency by at least 20 percent by the year 2005
- Increase of the use of solar and other renewable energy sources

The executive order also requires agencies to develop and implement programs to reduce the use of petroleum by switching to less-polluting non-petroleum-based energy sources, such as natural gas or solar energy sources. Where alternative sources are not practical, agencies are required to strive towards improving the efficiency of systems that currently use petroleum.

4.2 Programs for Energy Conservation

In order to reach the goals of the executive order, EPA must develop a program to introduce cost-effective and energy efficient technologies into its facilities.

By conducting surveys and audits, a laboratory can determine the effectiveness of energy conservation improvements and target new areas where improvements can be made. Each federal facility must have a 10-year plan to conduct or obtain comprehensive facility audits. These audits should also include a review of the energy conservation program in order to assess areas for energy conservation.

4.3 Guidelines for Facility Construction and Leasing

New facilities should be designed and constructed to meet or exceed any applicable energy conservation standards. The life-cycle cost of the facility can be conserved by using energy-efficient technologies.

New facilities should adopt active solar technologies whenever they are cost-effective.

When leasing facilities, the energy consumption of the facility and any provisions that will minimize the cost of energy should be identified, while maintaining or improving occupant safety and health. Negotiations on the cost of the lease should consider the reduced energy costs during the term of the lease.

4.4 Reporting Requirements

Laboratories should maintain all written programs, records, and documentation to confirm that the requirements of Executive Order 12902 are being met. This information must be available upon request.

4.5 Implementing Energy Conservation Techniques

There are many techniques that laboratories can apply to reduce energy consumption. These techniques include:

- Gaining employee involvement
- Using energy efficient equipment
- Implementing energy management techniques
- Instituting best-practice technologies

4.5.1 Employee Involvement

Laboratories should strive to involve employees and management in energy conservation programs. Useful techniques for gaining commitment and involvement include:

- Forming an energy team to help educate and motivate fellow employees
- Offering incentives for the best energy-saving strategy

- Reporting to employees how much energy costs decreased through their efforts

Energy teams, or environmental project teams, are useful in implementing energy efficiency. The Department of Energy offers training and support to help project teams develop expertise in energy savings.

4.5.2 Energy Efficient Equipment

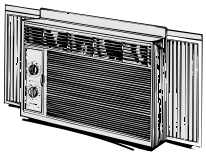
Laboratories may also consider other energy-saving techniques. For example,

they may ask electric utilities about rebates for energy-efficient lighting equipment. Motors are often oversized for jobs and can be replaced with smaller motors that use less energy. Office and laboratory equipment can often be replaced with equipment that runs more efficiently.

4.5.3 Energy Management Techniques

There are many specific techniques for energy-management that can be applied to reduce the amount of energy used in an EPA laboratory. These techniques fall under three categories: cooling, heating, and water heating, as discussed below.

Cooling



- Ensure air conditioners are the proper size for areas being cooled. (Regular maintenance, including a filter check, ensures efficient operation).

- Verify that windows are closed while air conditioning is in operation.

- Use automatic thermostats to adjust temperatures during off-work hours.

- Use drapes, shades, and awnings to reduce cooling costs by shielding windows from the hot sun.

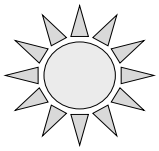
- Install energy-efficient windows to help keep cool air in and hot air out during summer months.

Heating

- Install energy-efficient windows to help prevent warm air from escaping.

- Insulate walls, ceilings, and floors to retain heat within the building.

- Caulk or weather-strip cracks in walls, floors, windows, and doors to avoid heat loss.



- Allow sunlight to enter laboratories by opening curtains, blinds, and shades. These should be re-closed during off-hours (evenings) to help retain heat.

Water Heating

- Lower the temperature of the water heater on weekends and holidays.

- Insulate water-heating systems and pipes to maintain warmth.

- Immediately repair leaks in pipes or faucets to conserve energy.

- If more than one boiler is used to heat the same area, sequence the boilers so only one is used when half the heating capacity is needed.

4.5.4 Best-Practice Technologies

In accordance with Department of Energy guidelines, all federal agencies must strive to purchase approved energy-efficient products. The guidelines that can be used specify practices to increase energy efficiency in federal agencies. Lists of energy efficient products are updated annually and agencies must increase, to the extent possible, purchases that are in the upper 25 percent of energy efficiency for all similar products, or products that are at least 10 percent more efficient that the minimum level that meets federal standards.

Attachment C9-1: Example P2 Projects

Purpose: To provide a sample of P2 projects for EPA laboratories.

Instructions: Compare current P2 program projects to the list to determine if there are additional P2 opportunities for the laboratory.

Attachment C9-1: Example P2 Projects

Facility	Example of P2 Projects
Laboratory	• Control sample sizes • Practice pH neutralization • Increase laboratory automation and implement new extraction techniques • Implement microanalytical techniques to reduce chemical quantities • Replace chemical-based methods with physical methods • Implement solid-phase extraction and high-pressure extraction practices to reduce amount of solvent purchased, used, and disposed of • Develop individual chambers to reduce gases used in inhalation techniques • Improve ventilation controls with fume hoods, biological safety cabinets, and clean benches • Eliminate excess ordering of animals
Offices and Regional Centers	• Compost lunch waste and coffee grounds • Substitute vinyl siding for wooden siding to reduce painting
Field Activity	• Send only required amount of analytes for analysis • Use biodegradable soap to clean field equipment
All Facilities	• Establish a heat reclamation process to harness the incinerator's excess energy for heating water • Landscape with indigenous plants, use mechanical means of weed control, use beetle bags instead of insecticide, use environmentally benign fertilizers, and increase mulching to decrease water use

1.0 Introduction

This chapter presents air quality regulations that may be applicable to an EPA laboratory assuming that it is not a "major source" of air pollutants. However, an EPA laboratory may still be subject to other regulatory requirements based on the air emissions sources present and/or the types of air emissions that they produce.

EPA Program Requirements

To ensure that it meets the applicable regulatory requirements, an EPA laboratory must consider whether, based on its design and operation, it is subject to the requirements for air quality outlined in this chapter relative to:

- Steam-generating units
- Radionuclide emissions
- Federal operating permit program
- Ozone-depleting substances
- Asbestos

Program Administration

To effectively manage an air quality program, an EPA laboratory should assign responsibility for the following items, as applicable:

Management of Change

- Assessing the regulatory implications of changes in laboratory design and/or operation

- Tracking changes to regulatory requirements that could potentially affect a laboratory

Permitting and Permit Requirements

- Ensuring that air emissions sources are permitted as required by governing regulatory requirements

- Ensuring compliance with the requirements established in the laboratory's air permit(s)

Air Emissions Monitoring

Monitoring quantities of nitrogen oxides, sulfur dioxide, particulate matter, and radionuclides.

Recordkeeping and Reporting

- Establishing and maintaining a recordkeeping system for information required by the governing regulations and/or air permit(s)

- Preparing and submitting notifications and report(s) to the EPA, as required

2.0 Management Systems

An EPA laboratory should thoroughly assess the actual and potential impacts that its air emissions have on the environment. Therefore, it can ensure that it does not allow the release of a substance in an amount, concentration, level, or rate of release that causes, or may cause, an exceedance of established air emission limitations and/or a significant adverse effect on the environment. In order to completely understand and effectively manage its air quality program, an EPA laboratory should perform an air emissions inventory, design programs and practices to control or minimize air emissions and perform air emissions prevention. Each are discussed in the following sections.

2.1 Air Emissions Inventory

Each EPA laboratory should perform an air emissions inventory. This involves preparing and maintaining a comprehensive listing of actual and potential air emissions (e.g., fume hoods, local vent pipes and stacks, drains) that includes the sources and locations of emission points, as well as analytical data characterizing the nature and volume of emissions. Sufficient documentation (i.e., process or equipment information) should be maintained so that the applicability of air permit requirements can be made. This determination should be made through the regulatory review process where the applicability of federal and state requirements is assessed.

2.2 Program and Practice Design

EPA laboratories should design and implement programs and practices for controlling and minimizing air emissions. This should include the full range of laboratory operations generating air emissions, such as sampling, equipment maintenance, start-up, and shutdown. Where feasible, the laboratory should consider establishing a program to apply appropriate technology (e.g., installation of air pollution control equipment on laboratory hoods, carbon canisters) to minimize or reduce the effects from emissions that cannot be otherwise eliminated.

2.3 Air Emissions Prevention

EPA laboratories can eliminate or reduce air emissions from their operations by considering emission control during process change, change of process scale, or modification of engineering controls.

3.0 Regulatory Requirements

This section addresses the regulatory requirements that are likely to apply to an EPA laboratory. There may be additional requirements that apply based on the nature of its processes, operations, etc. These requirements should be identified through a management of change process. In addition, this section addresses the EPA's proposal to regulate hazardous air pollutant (HAP) emissions from major research and development sources.

3.1 Federal Regulations

An EPA laboratory is not likely to be considered a "major source" of air pollution under the governing federal regulations based on its potential to emit less than 100 tons per year of a regulated pollutant. Therefore, it would not be subject to Pre-

vention of Significant Deterioration (PSD) or New Source Review (NSR) requirements. However, other federal regulatory programs that are potentially applicable to an EPA laboratory are summarized in Figure C10-1 and discussed in the following sections.

NSPS
The New Source Performance Standards (NSPS) in 40 CFR 60 establish requirements for new stationary sources of air pollution according to industry or emission source (e.g., steam generating units). This program is discussed in greater detail in section 4.0 of this chapter.

NESHAPs
The National Emission Standards for Hazardous Air Pollutants (NESHAPs) in 40 CFR 61 contains requirements governing emissions of specific pollutants (e.g., radionuclides, asbestos), regardless of source, process, or industry. These standards apply to both existing and new sources. This program is addressed in greater detail in section 5.0 of this chapter. Specific requirements related to asbestos are addressed in section 8.0 of this chapter.

Operating Permit Program
The operating permit program established under Title V of the 1990 Clean Air Act Amendments in 40 CFR 70 and 71 applies to major sources, as well as sources that are subject to NSPS or NESHAPs. This program is addressed in section 6.0 of this chapter.

Protection of Stratospheric Ozone Program
The Protection of Stratospheric Ozone Program established under 40 CFR 82 focuses on banning nonresidential uses of chlorofluorocarbons (CFCs), labeling containers that store Class I and II ozone-depleting substances, and certifying individuals who perform work on systems and equipment that contain CFCs. This program is addressed in section 7.0 of this chapter.

Even though all of the programs are federal programs, many states have been delegated regulatory authority for these programs by the EPA.

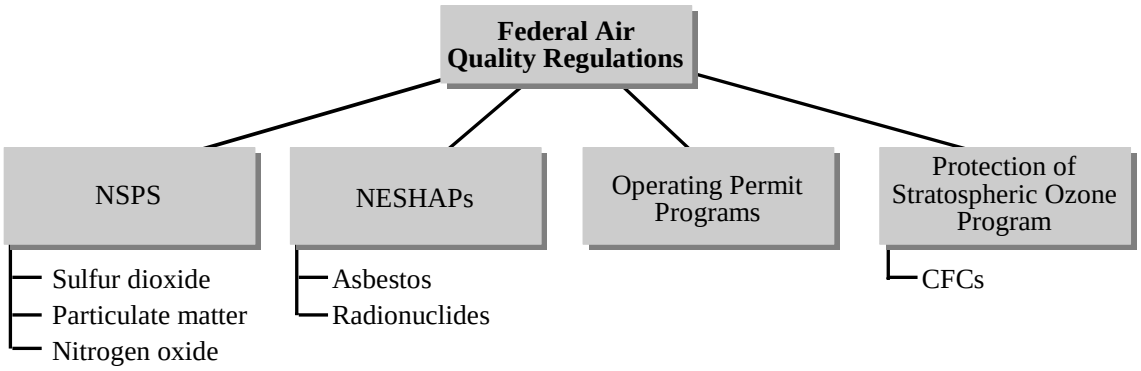
3.2 State and Local Regulations

In addition to the federal requirements, many states have established air-emission source requirements that may affect an EPA laboratory (e.g., permitting, state hazardous air pollutant inventory, and registration requirements). As such, an EPA laboratory should determine whether there are additional state and/or local requirements that may apply to its sources.

3.3 Proposed Regulations

The EPA has submitted a proposal to regulate HAP emissions from major research and development sources. As stated previously, an EPA laboratory is not likely to be considered a major source. However, based on the potential regulatory implications, an EPA laboratory should track the status of the EPA's proposal. The advance

Figure C10-1: Summary of the Applicable Air Emissions Regulations



notice of proposed rulemaking was published in the May 12, 1997 Federal Register. Possible regulatory requirements associated with EPA's proposal include:

- Maintaining records of chemical usage, inventory, and emissions for individual laboratories
- Installing air pollution control equipment on laboratory hoods
- Modifying laboratory procedures to minimize emissions
- Developing and implementing plans to reduce the usage of target chemicals (i.e., HAPs)

4.0 Steam Generating Units

A steam generating unit is an example of an air emissions source that may be present at an EPA laboratory. This section discusses the applicable regulatory requirements for the management of steam generating units.

4.1 Description of Steam Generating Units

There are three types of steam generating units that are discussed in the following sections: Subpart Db Units, Subpart A Units, and Subpart Dc Units.

4.1.1 Subpart Db Units

A steam generating unit for which construction, modification, or reconstruction commenced after June 19, 1984, that has a heat input capacity from fuels combusted in the unit of greater than 29 megawatts (i.e., 100 million British thermal units [Btu] per hour) is subject to NSPS, Subpart Db "Standards of Performance for Industrial–Commercial–Institutional Steam Generating Units."

4.1.2 Subpart A Units

Steam generating units that meet the criteria of Subpart Db are also subject to NSPS, Subpart A "General Provisions." This subpart includes specific require

ments relative to notifications; record-keeping and reporting; monitoring; performance tests; and control devices. It also addresses more general information pertaining to definitions, modification and reconstruction, and compliance with standards and maintenance requests.

4.1.3 Subpart Dc Steam Generating Units

A small steam generating unit for which construction, modification, or reconstruction commenced after June 9, 1989, that has a maximum design heat input capacity of 29 megawatts or less, but greater than or equal to 2.9 megawatts (i.e., 10 million Btu per hour) is subject to NSPS, Subpart Dc, "Standards of Performance for Small Industrial–Commercial–Institutional Steam Generating Units."

4.2 Sulfur Dioxide Emissions

Standards for sulfur dioxide emissions are set forth in 40 CFR 60.42b. Sulfur dioxide emission limitations vary based on the date of construction of the unit, the pollution control devices in place, and the fuel mixture. Affected EPA laboratories should determine if the emission limitations that apply to them.

4.2.1 Subpart Db Units

In the absence of such variations, sulfur dioxide emissions must be less than 10 percent of the potential sulfur dioxide emission rate, and less than the combined calculated emissions from the combustion of coal and oil for the Subpart Db units. The sulfur dioxide emission limitation for coal is 1.2 pounds per million Btu (lbs/MMBtu) and for oil is 0.8 lbs/MMBtu.

Note that only the heat input supplied to the unit from the combustion of coal and oil is counted. No credit is given for the heat input from the combustion of natural gas, wood, municipal-type solid waste, or other fuels, or heat input from exhaust gases from other sources such as gas turbines, kilns, etc. This standard applies to the unit during all phases of operation (i.e., startup, shutdown, etc.).

4.2.2 Subpart Dc Units

Sulfur dioxide emissions for a unit that burns only coal, such as Dc units, must be less than 10 percent of the potential sulfur dioxide emission rate, and less than 1.2 lb/MMBtu.

4.3 Particulate Matter Emissions

Particulate matter emission limits vary according to the fuel used. Table C10-1 presents the limits for particulate emissions from Subpart Db units that burn coal; oil or mixtures of oil with other fuels; and wood or mixtures of wood with other fuels (except coal). Table C10-2 presents limits for Subpart Dc Units.

The particulate matter and opacity standards apply at all times, except during periods of startup, shutdown, or malfunction. The annual capacity factor is determined by dividing the actual heat input to the unit during the calendar year from the combustion of coal, wood, or other fuels, as applicable, by the potential heat input to the unit if the unit had been operated for 8,760 hours at the maximum design heat input capacity.

4.4 Nitrogen Oxide Emissions

Standards for nitrogen oxide emissions that pertain to Subpart Db units are set forth in 40 CFR 60.44b. Nitrogen oxide emission limitations vary based on the fuel mixture. An affected EPA laboratory should ascertain the emission limitations that specifically apply to it.

4.5 Emission Monitoring

Emission monitoring requirements vary depending on the size of the unit and, in some cases, the governing state regulatory requirements. Some EPA laboratories may be allowed to calculate emissions based on process data and emission factors while others must install and maintain

Table C10-1: Limits for Particulate Emissions from Subpart Db Units

Fuel	Heat Input (lb/MMBtu)	Discussion
Coal-fired units	0.05	If the unit burns only coal, or if the unit burns coal and other fuels and has an annual capacity factor for the other fuels of 10 percent or less.
	0.10	If the unit burns coal and other fuels and has an annual capacity factor for the other fuels greater than 10 percent, and is subject to a federally enforceable requirement (limiting operation of the unit to an annual capacity factor greater than 10 percent for fuels other than coal)
	0.20	If construction of the unit commenced after June 19, 1984, and before November 25, 1986, and the unit burns coal or coal and other fuels and has: 1) an annual capacity factor for coal or coal and other fuels of 30 percent or less; 2) a maximum heat input capacity of 250 MMBtu/hr or less; and 3) a federally enforceable requirement limiting operation of the unit to an annual capacity factor of 30 percent or less for coal or coal and other solid fuels.
Oil or mixtures of oil with other fuels	0.10	None
Wood or mixtures of wood with other fuels (except coal)	0.10	If the unit has an annual wood capacity factor greater than 30 percent.
	0.20	If the unit: 1) has an annual capacity factor for wood of 30 percent or less; 2) is subject to a federally enforceable requirement limiting operation of the unit to an annual wood capacity factor of 30 percent or less; and 3) has a maximum heat input capacity of 250 MMBtu/hr or less.
Coal, oil, wood, or mixtures of these fuels with any other fuels	<20 percent opacity (6-minute average)	Except for one 6-minute period per hour of not more than 27 percent opacity.

Table C10-2: Limits for Particulate Emissions from Subpart Dc Units

Fuel	Heat Input (lb/MMBtu)	Discussion
Coal-fired units that have a heat input capacity of 30 MMBtu/hr or greater	0.05	If the unit burns only coal, or if the unit burns coal with other fuels and has an annual capacity factor for the other fuels of 10 percent or less.
	0.10	If the unit combusts coal with other fuels, has an annual capacity factor for the other fuels greater than 10 percent, and is subject to a federally enforceable requirement limiting operation of the unit to an annual capacity factor greater than 10 percent for fuels other than coal.
Wood or mixtures of wood with other fuels (except coal) that have a heat input capacity of 30 MMBtu/hr or greater	0.10	If the unit has an annual wood capacity factor that is greater than 30 percent, or 0.30 lb/MMBtu heat input if the unit has an annual wood capacity factor of 30 percent or less and is subject to a federally enforceable requirement limiting operation of the unit to an annual capacity factor for wood of 30 percent or less.
Coal, wood, or oil that have a heat input capacity of 30 MMBtu/hr or greater	<20 percent opacity (6-minute average)	Except for one 6-minute period per hour of not more than 27 percent opacity.

continuous emissions monitoring systems (CEMS). As such, an EPA laboratory's air permit should provide more detailed guidance regarding the emission monitoring requirements specifically applicable to the unit.

4.6 Reporting and Recordkeeping

The following sections discuss reporting and recordkeeping requirements for steam generating units.

4.6.1 Subpart Db Units

An EPA laboratory with unit(s) that are subject to Subpart Db is also subject to the NSPS, Subpart A "General Provisions." This subpart includes specific requirements relative to notification; recordkeeping and reporting; monitoring; performance tests; and control devices.

An EPA laboratory with unit(s) subject to Subpart Db should provide the following information to the EPA:

- The date of construction within 30 days after such date
- The anticipated date of initial startup between 30 to 60 days prior to such date
- The actual date of initial startup within 15 days after such date

EPA laboratories must maintain records of the amounts of each type of fuel burned during each day. Also the annual capacity factor must be calculated individually for coal, distillate oil, residual oil, natural gas, wood, and municipal-type solid waste for each calendar quarter. The annual-capacity factor is determined on a 12-month rolling average basis with a new annual-capacity factor calculated at the end of each calendar month.

Records of fuel nitrogen content and nitrogen oxide emissions are required for certain units. Excess emissions reports are required and must be submitted semiannually or for every calendar quarter and include information required under 40 CFR 60.7(c), such as:

- The magnitude of excess emissions
- The date and time period of each excess emissions event
- The nature and cause of each malfunction leading to excess emissions, and the corrective actions taken
- The date and time that the CEMS was not operating

In general, an EPA laboratory should retain any process data that is required to demonstrate compliance with established emission limits.

4.6.2 Subpart Dc Units

An EPA laboratory with unit(s) subject to Subpart Dc should provide the following information to the EPA:

- Date of construction within 30 days after such date
- Anticipated date of initial startup between 30 to 60 days prior to such date
- Actual date of initial startup within 15 days after such date
- Design heat input capacity
- Fuels to be burned
- Any federally enforceable requirement that limits the annual capacity factor for any fuel or mixture of fuels
- Annual capacity factor at which the owner or operator anticipates operating the affected facility

An EPA laboratory that has a unit subject to the sulfur dioxide emission limits under 40 CFR 60.42c, or the particulate matter or opacity limits under 40 CFR 60.43c, shall submit the performance test data from the initial (and any subsequent) performance tests and, if applicable, the performance evaluation of the CEMS to the EPA.

Laboratories that have a coal-fired, residual oil-fired, or wood-fired unit subject to the opacity limits under 40 CFR 60.43(c) shall submit excess-emission reports to the EPA for any calendar quarter for which there are excess emissions. If there are no excess emissions during the calendar quarter, the owner or operator shall submit a report semiannually stating that no excess emissions occurred during the semiannual reporting period. The time frames for reporting are listed as follows:

- The ***initial quarterly report*** must be postmarked by the 30th day of the third month following the completion of the initial performance test, unless no excess emissions occur during that quarter.

- The ***initial semiannual report*** must be postmarked by the 30th day of the sixth month following the completion of the initial performance test, or following the date of the previous quarterly report, as applicable.

- Each ***subsequent quarterly or semiannual report*** must be postmarked by the 30th day following the end of the reporting period.

- An EPA laboratory that has a unit subject to the sulfur dioxide emission limits, fuel oil sulfur limits, or percentage-reduction requirements under 40 CFR 60.43c shall:

  — Submit quarterly reports to the EPA. (The initial quarterly report shall be postmarked by the 30th day of the third month following the completion of the initial performance test. Each subsequent quarterly report shall be postmarked by the 30th day following the end of the reporting period.)

  — Keep the required records and submit quarterly reports as specified in this section.

- An EPA laboratory should also record and maintain records of the amounts and types of fuel burned during each day.

In general, an EPA laboratory should retain any process data that is required to demonstrate compliance with established emission limitations.

5.0 Radionuclide Emissions

In general, radionuclide emissions are regulated by the Nuclear Regulatory Commission (NRC) or NRC Agreement State. Emissions specific to the laboratory may be listed in a laboratory's NRC radioactive materials license. If an EPA laboratory does not have an NRC license, then its radionuclide emissions are subject to NESHAPs, 40 CFR 61, Subpart I, "National Emission Standards for Radionuclide Emissions from Federal Facilities Other than Nuclear Regulatory Commission Licensees and Not Covered by Subpart H."

5.1 Emission Limits

Emissions of radionuclides, excluding iodine, into the ambient air must not exceed those amounts that would cause any member of the public to receive in any year an effective dose equivalent of 10 millirem per year. Emissions of iodine to the ambient air from a facility regulated under this subpart shall not exceed those amounts that would cause any member of the public to receive in any year an effective dose equivalent of 3 millirem.

5.2 Monitoring

Compliance with the emission standard must be determined with either the EPA computer model COMPLY or alternative requirements in 40 CFR 61, Appendix E that requires an inventory of radioactive

materials. Facilities emitting radionuclides not listed in COMPLY or Appendix E shall contact the EPA to receive the information needed to determine the dose.

Facilities may demonstrate compliance with the emission standard through the use of computer models that are equivalent to COMPLY, provided that the model has received prior approval from EPA headquarters. Any facility using a model other than COMPLY must file an annual report. The EPA may approve an alternative model in whole or in part and may limit its use to specific circumstances.

5.3 Reporting

An annual report to the EPA is required covering the radionuclide emissions of a calendar year by March 31 of the following year. It must include the following information:

- The name of the facility
- The name of the person responsible for operating the facility and the name of the person preparing the report (if different)
- The location of the facility, including suite and/or building number, street, city, county, state, and zip code
- The mailing address of the facility, if different from the facility location
- A list of the radioactive materials used at the facility
- A description of radioactive materials handling and processing at the facility
- A list of the stacks, vents, or other points where radioactive materials are released into the atmosphere
- A description of the effluent controls that are used on each stack, vent, or other release point and an estimate of the efficiency of each device
- Distances from the point of release to the nearest residence, school, business, or office, and the nearest farms producing vegetables, milk, and meat
- The effective dose equivalent calculated using the COMPLY model
- The physical form and quantity of each radionuclide emitted from each stack, vent, or other release point, and the method(s) by which these quantities were determined
- The volumetric flow, diameter, effluent temperature, and release height for each stack, vent or other release point where radioactive materials are emitted, and the method(s) by which these were determined
- The height and width of each building from which radionuclides are emitted
- The values used for all other user-supplied input parameters (e.g., meteorological data) and the source of the data
- A brief description of all construction and modifications that were completed in the calendar year for which the report is prepared, but for which the requirement to apply for approval

to construct or modify was waived under 40 CFR 61.106, and associated documentation developed by the licensee to support the waiver

Each report must be signed and dated by a corporate officer or public official in charge of the facility and contain the following declaration immediately above the signature line:

> "I certify, under penalty of law, that I have personally examined and am familiar with the information submitted herein and, based on my inquiry of those individuals immediately responsible for obtaining the information, I believe that the submitted information is true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment."

Facilities emitting radionuclides in an amount that would cause less than 10 percent of the dose standard are exempt from the reporting requirements. Facilities must annually determine whether they are exempt from reporting.

5.4 Recordkeeping

EPA laboratories must keep records that document the source of input parameters, including the results of all measurements on which they are based, the calculations and/or analytical methods used to derive values for input parameters, and the procedure used to determine compliance. This documentation should be sufficient to allow an independent auditor to verify the accuracy of the determination made concerning the facility's compliance with the standard, and, if claimed, qualification for exemption from reporting. These records must be kept at the site of the facility for at least five years and must be made available for inspection upon request.

6.0 Federal Operating Permit Program

The Federal Operating Permit Program established under Title V of the 1990 Clean Air Act Amendments in 40 CFR 70 and 71 applies to major sources, as well as sources that are not major sources but are subject to certain subparts of the NSPS or NESHAPs regulations. However, an EPA laboratory that is subject to any of the NSPS or NESHAPs subparts addressed above is required to be considered in the Title V permit program. This program will be administered either by the EPA, via the regulations established in 40 CFR 71, or a state agency that has been delegated authority for the program by the EPA, via the state air permitting regulations.

7.0 Ozone-Depleting Substances

An EPA laboratory that has processes or equipment that contain CFCs should:

- Compile and maintain a sitewide inventory of CFCs used in the laboratory's air conditioning and refrigeration systems and other processes.
- Maintain records to demonstrate that personnel, including contractors, who perform maintenance on the laboratory's air conditioning and re-

frigeration systems have been trained and certified to perform this work, and, if applicable, that they use certified recycling and recovery equipment.

- Maintain records related to certified refrigerant recycling equipment, for at least three years, that include the name and address of any facility to which refrigerant is sent.

- For equipment containing 50 pounds or more of refrigerant, maintain service records for at least three years, that document the date and time of service as well as the quantity of refrigerant added, or, in cases where the EPA laboratory adds its own refrigerant, records of the refrigerant purchased.

8.0 Asbestos

Specific asbestos activities are subject to NESHAPs, 40 CFR 61, Subpart M, "National Emission Standard for Asbestos." The federal standards governing asbestos activities (e.g., manufacturing, demolition and renovation, spraying, fabricating, and insulating) that may pertain to an EPA laboratory are in 40 CFR 61.140 through 61.148. If an EPA laboratory engages in any of these activities, it should refer to the regulatory requirements specified in 40 CFR 61.150 through 61.153 that address waste disposal, air cleaning, and reporting. Refer to Chapter C14 of this manual for more information on waste management.

An EPA laboratory that meets the criteria of Subpart M is also subject to NESHAPs, 40 CFR 61, Subpart A, "General Provisions." This subpart includes specific requirements relative to notifications, monitoring, and emission tests, and also addresses more general information pertaining to definitions, construction or modification, and compliance with standards and maintenance requests.

1.0 Introduction

The Emergency Planning and Community Right-To-Know Act (EPCRA) was designed to inform emergency planners and the public of potential chemical hazards. The regulations were developed to provide the following information about hazardous chemicals or extremely hazardous substances:

- The quantity of regulated chemicals at the laboratory
- The specific hazards presented by the chemicals
- The fate of chemicals (i.e., used, discharged, sold, etc.)
- Any unplanned releases

Under the emergency planning provisions, state emergency response commissions, and local emergency planning committees (LEPCs) must be established. These authorities are mandated to develop and implement plans for responding to emergencies. Laboratories subject to the emergency planning provisions are required to inform the state and local emergency response authorities that extremely hazardous substances are on-site. They must also work with the LEPC on planning for emergencies.

The regulations require a variety of reports, which are discussed in this chapter:

- Tier I/Tier II Reporting
- Release Reporting
- Toxic Release Inventory Reporting
- Material Safety Data Sheets

EPA Program Requirements

To ensure that reporting requirements of EPCRA are met, EPA laboratories must evaluate the mandates for applicability of:

- Tier I/Tier II Reporting
- Release Reporting
- Toxic Release Inventory Reporting
- Material Safety Data Sheets

Program Administration

To effectively manage an EPCRA program, responsibilities should be assigned for the following:

Tier I/Tier II Reporting

- Identifying all chemicals regulated under EPCRA, with average as well as maximum amounts on-site
- Determining if any reporting thresholds have been exceeded
- Submitting required reports

Release Reporting

- Filing appropriate reports for any release of toxic substance(s)
- Notifying community emergency coordinators in areas that may be affected by a release
- Providing a follow-up notice if an emergency notice has been filed

Toxic Release Inventory (TRI) Reporting

- Determining if TRI reporting is applicable to the laboratory

- Determining and documenting the amount of regulated toxic substance(s) in air and water effluents, waste, and byproducts

- Developing and maintaining required records

- Filing reports to the EPA when necessary

Material Safety Data Sheets (MSDSs)

- Determining if MSDSs for the hazardous chemicals on-site must be submitted to local agencies

2.0 Tier I/Tier II Reporting

Figure C11-1 provides a summary of the Tier I and Tier II inventory form submission determination process as required by 40 CFR 370.20.

A Tier I form requires a certification statement, information on the maximum amount of chemicals at the laboratory during the year, the daily average amount on-site, number of days on-site, and information on hazard type and storage location for all chemicals subject to the requirements.

The Tier II inventory reporting form contains more detailed information on hazardous chemicals and extremely hazardous substances. Figure C11-2 provides a summary of the information required on both the Tier I and Tier II forms. EPA laboratories may complete the simpler Tier I form, unless the EPA or state agencies request a Tier II form.

Emergency planning agencies may request information for hazardous chemicals that may occur on-site below the reporting thresholds.

Each EPA laboratory should identify all of the chemicals on-site that are regulated under EPCRA and maintain a detailed inventory of the average and maximum amounts present. The items presented in Table C11-1 are exempt from hazardous-chemical reporting requirements of 40 CFR 370.20.

At the end of the year, laboratories must examine the inventory and determine if any of the reporting thresholds have been exceeded. The basis for the decisions should be documented and maintained with supporting documentation.

Figure C11-1: Tier I and II Inventory Form Submission

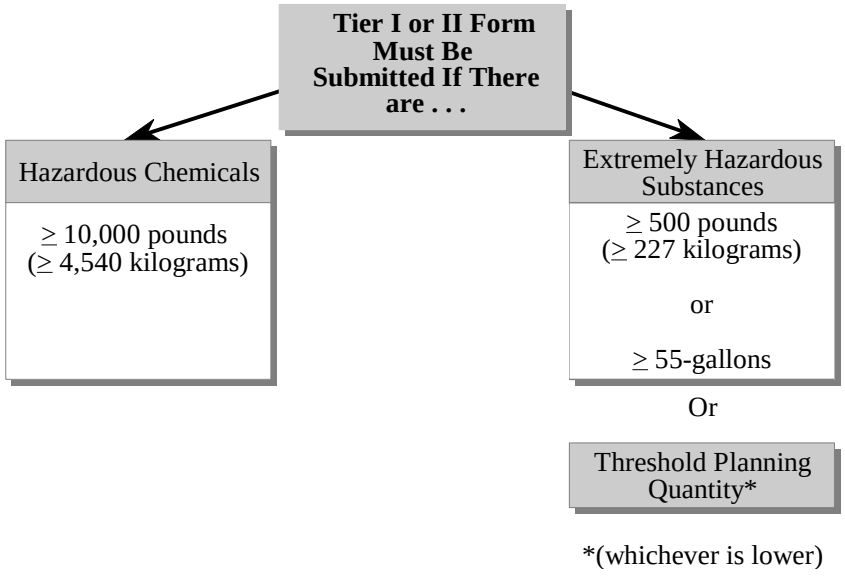


Figure C11-2: Summary of Information Required on Inventory Reporting Forms

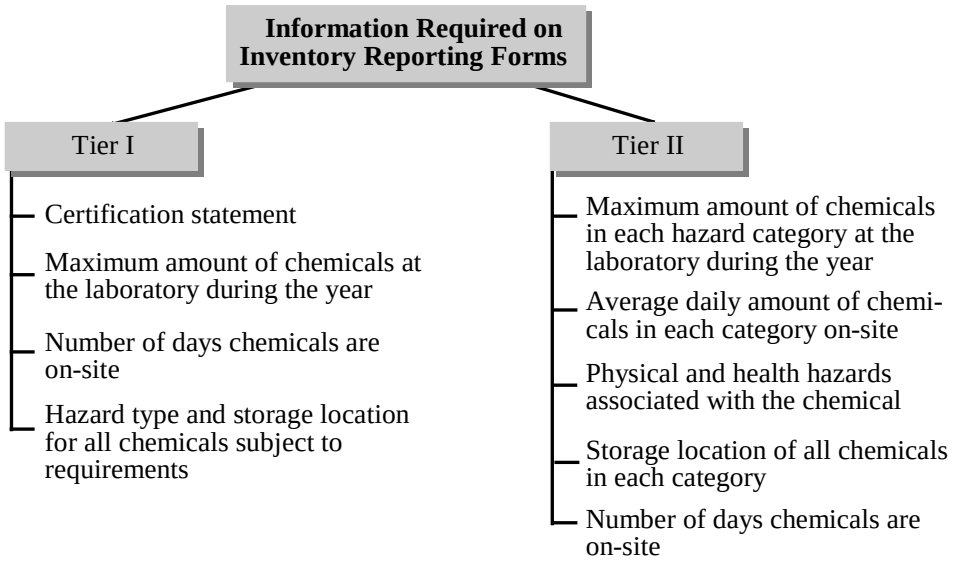


Table C11-1: Items That Are Exempt From Hazardous-Chemical Reporting Requirements

Item	Description
HAZCOM-Excluded Substances	Substances excluded from the coverage of the OSHA Hazard Communication Standard (HAZCOM)
FDA-Regulated Substances	Any food or food-color additive, drug, or cosmetic regulated by the Food and Drug Administration (FDA)
Articles	Substances present as a solid in any manufactured item as long as exposure to the substance does not occur under normal conditions of use (e.g., asbestos insulation and polychlorinated biphenyls [PCBs] in transformers)
Household Products	Substances used for personal, family, or household purposes or present in the same form and concentration as products packaged for distribution and use by the general public
Research Laboratory Substances	Substances used in a research laboratory, hospital, or under the direct supervision of a technically qualified individual
Agricultural Substances	Substances used in routine agricultural operations, or fertilizers held by a retailer for sale to the ultimate customer

The Tier I/II reporting forms are available from the EPA. Examples of the forms are included in Attachment C11-1. The laboratory must submit an inventory form to the Agency, the committee, and the fire department with jurisdiction over the laboratory before March 1 of the following year.

The laboratory must allow on-site inspection upon request of the fire department having jurisdiction over the laboratory, and must provide the location of hazardous chemicals at the laboratory to the department.

3.0 Release Reporting

This section applies to any laboratory where a hazardous chemical is produced, used, or stored and at which there is a release of a reportable quantity of any extremely hazardous substance listed in 40 CFR 355 or any hazardous substance as defined in 40 CFR 302.

This section does not apply to:

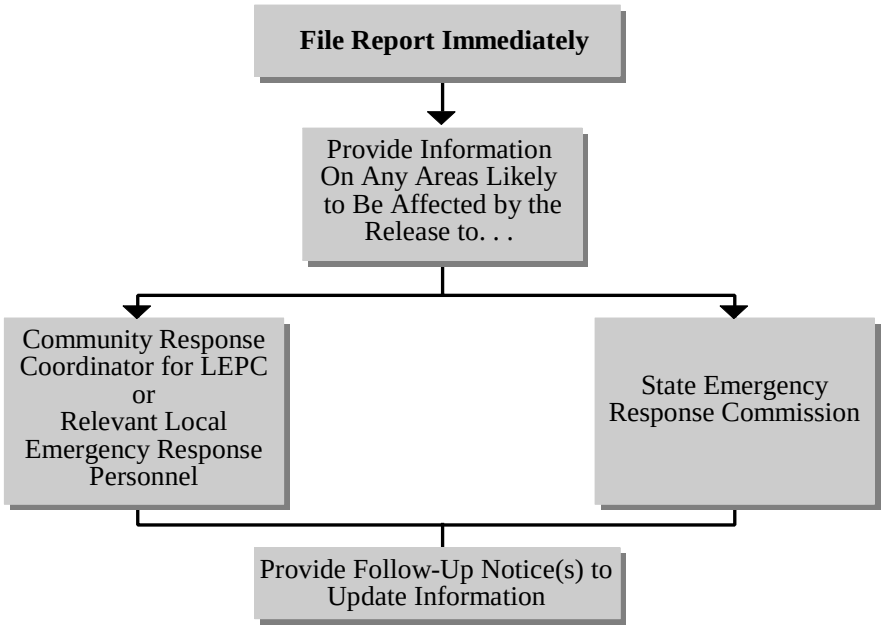
- Any release that is continuous and stable in quantity and rate under the definitions in 40 CFR 302.8(b)
- Any release that results in exposure to persons solely within the boundaries of the laboratory
- Any release that is a "federally permitted release" as defined in section 101 (10) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)

If the laboratory experiences a release of a toxic substance, a report should be filed immediately, even if the amount of the release is undetermined. The notification can be retracted later if investigations show that the release is below the reporting threshold. Figure C11-3 summarizes the notification of emergency officials.

The notice must include the following information to the extent known at the time of notice and provided that no delay in notice or emergency response results:

- The chemical name or identity of any substance involved in the release
- An indication of whether the substance is an extremely hazardous substance
- An estimate of the quantity of the substance that was released into the environment
- The time and duration of the release
- The medium or media into which the release occurred
- Any known or anticipated acute or chronic health risks associated with the emergency and, where appropriate, advice regarding medical attention necessary for exposed individuals
- Proper precautions to take as a result of the release, including evacuation, unless this information is readily available to the LEPC

Figure C11-3: Toxic Substance Release Notification



- The names and telephone number of the person or persons to be contacted for further information

The laboratory must then provide a written follow-up notice(s), as soon as possible. These follow-ups update the information required in the notice and include additional information on:

- Actions taken to respond to, and contain, the release
- Any known or anticipated acute or chronic health risks associated with the release
- Advice regarding medical attention necessary for exposed individuals, where appropriate

4.0 TRI Reporting

A laboratory that meets all of the following criteria for a calendar year is a covered laboratory for that calendar year and must comply with TRI reporting requirements in 40 CFR 372:

- The laboratory has 10 or more full-time employees
- The laboratory is in Standard Industrial Classification Codes 20 through 39.
- The laboratory manufactured, imported, processed, or otherwise used a toxic chemical in excess of an applicable threshold quantity of that chemical

Thresholds for reporting are as follows:

- For a toxic chemical manufactured (including imported) or processed at a laboratory—25,000 pounds of the

chemical manufactured or processed for the year

- For a chemical otherwise used at a laboratory—10,000 pounds of the chemical used for the applicable calendar year

EPA laboratories may qualify for an exemption for TRI reporting. If a toxic chemical is manufactured, processed, or used in a laboratory under the supervision of a technically qualified individual, the quantity of the particular chemical does not have to be considered when determining whether an applicable threshold has been met, or in determining the amount of release to be reported.

This exemption does not apply in the following cases:

- Specialty chemical production
- Manufacture, processing, or use of toxic chemicals in pilot plant–scale operations, where the product is distributed into commerce (that is, if the pilot plant is solely for research and development, then the laboratory exemption still applies)
- Activities conducted outside the laboratory

If the laboratory does not qualify for this exemption, then it should evaluate the applicability of other exemptions (e.g., de minimus, articles, uses) by referring to 40 CFR 372.38.

The TRI regulations can be viewed as a mass balance for all hazardous and extremely hazardous substances manufactured, processed, or otherwise used by the laboratory. Thus it is important to document the amount of a regulated toxic substance in air and water effluents, waste, and byproducts. The regulations do not specify minimum requirements for data accuracy but it is sometimes necessary to sample effluents to determine the amount of material emitted through any given pathway.

The laboratory must develop and maintain the documentation listed in Table C11-2 for three years.

For each toxic chemical manufactured, imported, processed, or otherwise used in excess of an applicable threshold quantity, the laboratory must file a completed EPA Form R (EPA Form 9350-1) in accordance with the instructions referred to in 40 CFR 372, Subpart E. An example of EPA Form R is included in Attachment C11-2. Note that, in the case of mixtures of toxic chemicals with other chemicals, only the amount of the toxic chemical present in the mixture needs to be included.

The report must be submitted on or before July 1 of the following year.

5.0 Material Safety Data Sheets

The following requirements apply to any facility required to prepare or have available an MSDS for a hazardous chemical under the Occupational Safety and Health Act (OSHA) of 1970 and regulations promulgated under that Act. Each laboratory must identify, and submit an MSDS for,

Table C11-2: TRI Documentation

TRI Documentation Required to be Developed and Maintained
• TRI reports submitted and supporting documentation • Determination that laboratory is a covered facility • Documentation of an allowable exemption • Determination of whether a threshold under $372.25 applies for each toxic chemical • Calculation of the quantity of each toxic chemical released to the environment or transferred to an off-site location • Supporting information for use indications and quantity on-site reporting for each toxic chemical (e.g., dates of manufacture, processing, or use) • Basis for estimate used in developing any release or off-site transfer estimates for each toxic chemical • Receipts or manifests associated with the transfer to off-site locations of each toxic chemical in waste • Estimates of waste treatment efficiency for each toxic chemical such as: reported waste treatment methods, estimates of treatment efficiencies, ranges of influent concentration to such treatment, sequential nature of treatment steps, and actual operating data

the following substance:

- All extremely hazardous substances present at the laboratory at any one time in amounts greater than, or equal to, 500 pounds or the threshold planning quantity (TPQ) listed in the Appendix to 40 CFR 355, whichever is less (An excerpt from this Appendix is included as Attachment C11-3 to this manual)

- All hazardous chemicals (for which MSDSs are required) present at the laboratory at any one time in an amount greater than or equal to 10,000 pounds.

MSDSs for hazardous chemicals present at the laboratory above the applicable threshold must be submitted to the LEPC, the state emergency response commission, and the fire department with jurisdiction over the facility.

Alternatively, the laboratory may submit the following:

- A list of the hazardous chemicals for which MSDSs are required, grouped by hazard category

- The chemical or common name of each hazardous chemical as provided on the MSDS

- Any hazardous component of each hazardous chemical as provided on the MSDS

- A revised MSDS to the committee, the commission, and the fire department within three months after discovery of new information on the chemical

Attachment C11-1: Sample Tier I/II Forms

Purpose: To provide an example of Tier I/II inventory reporting forms.

Instructions: Obtain the appropriate form from the EPA and submit it to the Agency, the committee, and the fire department with jurisdiction over the laboratory.

Revised June 1990

Page _____ of _____ pages
Form Approved OMB No. 2050-0072

Tier One

EMERGENCY AND HAZARDOUS CHEMICAL INVENTORY

Aggregate Information by Hazard Type

FOR OFFICIAL USE ONLY

ID #

Date Received

Important: Read instructions before completing form

Reporting Period From January 1 to December 31, 19____

Facility Identification

Name _____

Street _____

City _____ **County** _____ **State** _____ **Zip** _____

SIC Code ☐☐☐☐ **Dun & Brad Number** ☐☐-☐☐☐-☐☐☐☐

Owner/Operator

Name _____

Mail Address _____

Phone (_____)

Emergency Contacts

Name _____

Title _____

Phone (_____)

24-Hour Phone (_____)

Name _____

Title _____

Phone (_____)

24-Hour Phone (_____)

☐ Check if information below is identical to the information submitted last year.

☐ Check if site plan is attached

	Hazard Type	*Max Amount**	*Average Daily Amount**	*Number of Days On-Site*	*General Location*
Physical Hazards	Fire	☐☐	☐☐	☐☐☐	
	Sudden Release of Pressure	☐☐	☐☐	☐☐☐	
	Reactivity	☐☐	☐☐	☐☐☐	
Health Hazards	Immediate (acute)	☐☐	☐☐	☐☐☐	
	Delayed (chronic)	☐☐	☐☐	☐☐☐	

Certification *(Read and sign after completing all sections)*

I certify under penalty of law that I have personally examined and am familiar with the information submitted in pages one through _____, and that based on my inquiry of those individuals responsible for obtaining the information, I believe that the submitted information is true, accurate and complete.

_____

Name and official title of owner/operator OR owner/operator's authorized representative

_____ _____

Signature Date signed

***Reporting Ranges**

Range Code	Weight Range in Pounds From...	To...
01	0	99
02	100	999
03	1000	9,999
04	10,000	99,999
05	100,000	999,999
06	1,000,000	9,999,999
07	10,000,000	49,999,999
08	50,000,000	99,999,999
09	100,000,000	499,999,999
10	500,000,000	999,999,999
11	1 billion	higher than 1 billion

Page ______ of ______ pages
Form Approved OMB No. 2050-0072

Revised June 1990

Tier Two
EMERGENCY AND HAZARDOUS CHEMICAL INVENTORY

Specific Information by Chemical

Facility Identification

Name ______________________

Street ______________________

City ________ County ________ State ______ Zip ______

SIC Code ☐☐☐☐ Dun & Brad Number ☐☐-☐☐☐-☐☐☐☐

FOR OFFICIAL USE ONLY ID # ______ Date Received ______

Owner/Operator Name

Name ______________ Phone ( ) ______

Mail Address ______________________

Emergency Contact

Name ______________ Title ______________

Phone ( ) ______ 24-Hr. Phone ( ) ______

Name ______________ Title ______________

Phone ( ) ______ 24-Hr. Phone ( ) ______

Important: Read all instructions before completing form

Reporting Period From January 1 to December 31, 19____

☐ Check if information below is identical to the information submitted last year.

Chemical Description	Physical and Health Hazards (check all that apply)	Inventory	Container Type / Temperature / Pressure	Storage Codes and Locations (Non-Confidential) *Storage Locations*	Optional
CAS ☐☐☐☐☐☐-☐☐-☐ Trade Secret ☐ Chem. Name ______ *Check all that apply:* ☐ Pure ☐ Mix ☐ Solid ☐ Liquid ☐ Gas ☐ EHS EHS Name ______	☐ Fire ☐ Sudden Release of Pressure ☐ Reactivity ☐ Immediate (acute) ☐ Delayed (chronic)	☐☐ Max. Daily Amount (code) ☐☐ Avg. Daily Amount (code) ☐☐☐ No. of Days On-site (days)			☐
CAS ☐☐☐☐☐☐-☐☐-☐ Trade Secret ☐ Chem. Name ______ *Check all that apply:* ☐ Pure ☐ Mix ☐ Solid ☐ Liquid ☐ Gas ☐ EHS EHS Name ______	☐ Fire ☐ Sudden Release of Pressure ☐ Reactivity ☐ Immediate (acute) ☐ Delayed (chronic)	☐☐ Max. Daily Amount (code) ☐☐ Avg. Daily Amount (code) ☐☐☐ No. of Days On-site (days)			☐
CAS ☐☐☐☐☐☐-☐☐-☐ Trade Secret ☐ Chem. Name ______ *Check all that apply:* ☐ Pure ☐ Mix ☐ Solid ☐ Liquid ☐ Gas ☐ EHS EHS Name ______	☐ Fire ☐ Sudden Release of Pressure ☐ Reactivity ☐ Immediate (acute) ☐ Delayed (chronic)	☐☐ Max. Daily Amount (code) ☐☐ Avg. Daily Amount (code) ☐☐☐ No. of Days On-site (days)			☐

Certification *(Read and sign after completing all sections)*

I certify under penalty of law that I have personally examined and am familiar with the information submitted in pages one through ______, and that based on my inquiry of those individuals responsible for obtaining the information, I believe that the submitted information is true, accurate and complete.

Name and official title of owner/operator OR owner/operator's authorized representative ______ Signature ______ Date signed ______

Optional Attachments

☐ I have attached a site plan
☐ I have attached a list of site coordinate abbreviations
☐ I have attached a description of dikes and other safeguard measures

Form Approved OMB No. 2050-0072

Revised June 1990

Tier Two

EMERGENCY AND HAZARDOUS CHEMICAL INVENTORY

Specific Information by Chemical

Facility Identification

Name _____

Street _____

City _____ County _____ State _____ Zip _____

SIC Code ☐☐☐☐ Dun & Brad Number ☐☐-☐☐☐-☐☐☐☐

FOR OFFICIAL USE ONLY

ID #

Date Received

Owner/Operator Name

Name _____ Phone ( )

Mail Address _____

Emergency Contact

Name _____ Title _____

Phone ( ) 24-Hr. Phone ( )

Name _____ Title _____

Phone ( ) 24-Hr. Phone ( )

Important: Read all instructions before completing form

Reporting Period From January 1 to December 31, 19____

☐ Check if information below is identical to the information submitted last year.

Confidential Location Information Sheet

Storage Codes and Locations (Confidential)

Storage Locations

Container Type / Temperature / Pressure

Optional

CAS # ☐☐☐☐☐☐-☐☐ Chem. Name

CAS # ☐☐☐☐☐☐-☐☐ Chem. Name

CAS # ☐☐☐☐☐☐-☐☐ Chem. Name

Certification *(Read and sign after completing all sections)*

I certify under penalty of law that I have personally examined and am familiar with the information submitted in pages one through _____, and that based on my inquiry of those individuals responsible for obtaining the information, I believe that the submitted information is true, accurate and complete.

Name and official title of owner/operator OR owner/operator's authorized representative

Signature

Date signed

Optional Attachments

☐ I have attached a site plan

☐ I have attached a list of site coordinate abbreviations

☐ I have attached a description of dikes and other safeguard measures

Attachment C11-2: Sample EPA Form R

Purpose: To provide an example of EPA Form R, which serves as a report of the laboratory's toxic chemicals manufactured, processed, or used in excess of threshold quantities.

Instructions: Obtain the form from the EPA, and complete it in accordance with 40 CFR 372, Subpart E.

Form Approved OMB Number: 2070-0093
Approval Expires: 04/2000

EPA FORM R

United States Environmental Protection Agency

TOXIC CHEMICAL RELEASE INVENTORY REPORTING FORM

Section 313 of the Emergency Planning and Community Right-to-Know Act of 1986, also known as Title III of the Superfund Amendments and Reauthorization Act

WHERE TO SEND COMPLETED FORMS: 1. EPCRA Reporting Center, P.O. Box 3348, Merrifield, VA 22116-3348, ATTN: TOXIC CHEMICAL RELEASE INVENTORY; 2. APPROPRIATE STATE OFFICE (See instructions in Appendix F)

Enter "X" here if this is a revision ☐

For EPA use only

IMPORTANT: See instructions to determine when "Not Applicable (NA)" boxes should be checked.

PART I. FACILITY IDENTIFICATION INFORMATION

SECTION 1. REPORTING YEAR 19 ____

SECTION 2. TRADE SECRET INFORMATION

2.1 Are you claiming the toxic chemical identified on page 2 trade secret? ☐ Yes (Answer question 2.2; Attach substantiation forms) ☐ No (Do not answer 2.2; go to Section 3)

2.2 Is this copy ☐ Sanitized ☐ Unsanitized (Answer only if "YES" in 2.1)

SECTION 3. CERTIFICATION (Important: Read and sign after completing all form sections.)

I hereby certify that I have reviewed the attached documents and that, to the best of my knowledge and belief, the submitted information is true and complete and that the amounts and values in this report are accurate based on reasonable estimates using data available to the preparers of this report.

Name and official title of owner/operator or senior management official:	Signature:	Date signed:

SECTION 4. FACILITY IDENTIFICATION

TRI Facility ID Number:

4.1 Facility or Establishment Name:

Facility or Establishment Name or Mailing Address (if different from street address):

Street:

Mailing Address:

City/County/State/Zip Code:

City/County/State/Zip Code:

4.2 This report contains information for: (Important: check a or b; check c if applicable) a. ☐ An entire facility b. ☐ Part of a facility c. ☐ A Federal facility

4.3 Technical Contact Name: Telephone Number (include area code):

4.4 Public Contact Name: Telephone Number (include area code):

4.5 SIC Code(s) (4 digits): a. b. c. d. e. f.

4.6	Degrees	Minutes	Seconds		Degrees	Minutes	Seconds
Latitude				Longitude			

4.7 Dun & Bradstreet Number(s) (9 digits)	4.8 EPA Identification Number(s) (RCRA I.D. No.) (12 characters)	4.9 Facility NPDES Permit Number(s) (9 characters)	4.10 Underground Injection Well Code (UIC) I.D. Number(s) (12 digits)
a.	a.	a.	a.
b.	b.	b.	b.

SECTION 5. PARENT COMPANY INFORMATION

5.1 Name of Parent Company ☐ NA

5.2 Parent Company's Dun & Bradstreet Number ☐ NA (9 digits)

EPA FORM R
PART II. CHEMICAL - SPECIFIC INFORMATION

TRI FACILITY ID NUMBER

Toxic Chemical, Category, or Generic Name

SECTION 1.TOXIC CHEMICAL IDENTITY

(Important: DO NOT complete this section if you completed Section 2 below.)

1.1	CAS NUMBER (IMPORTANT: Enter only one number exactly as it appears on the Section 313 list. Enter category code if reporting a chemical category.)
1.2	Toxic Chemical or Chemical Category Name (Important: Enter only one name exactly as it appears on the Section 313 list.)
1.3	Generic Chemical Name (Important: Complete only if Part I, Section 2.1 is checked "yes". Generic name must be structurally descriptive.)

SECTION 2. MIXTURE COMPONENT IDENTITY

(Important: DO NOT complete this section if you complete Section 1 above.)

2.1	Generic Chemical Name Provided by Supplier (Important: Maximum of 70 characters, including numbers, letters, spaces, and punctuation.)

SECTION 3. ACTIVITIES AND USES OF THE TOXIC CHEMICAL AT THE FACILITY (Important: Check all that apply.)

3.1 Manufacture the toxic chemical:	3.2 Process the toxic chemical:	3.3 Otherwise use the toxic chemical:
a. ☐ Produce b. ☐ Import		
If produce or import:		
c. ☐ For on-site use/processing	a. ☐ As a reactant	a. ☐ As a chemical processing aid
d. ☐ For sale/distribution	b. ☐ As a formulation component	b. ☐ As a manufacturing aid
e. ☐ As a byproduct	c. ☐ As an article component	c. ☐ Ancillary or other use
f. ☐ As an impurity	d. ☐ Repackaging	

SECTION 4. MAXIMUM AMOUNT OF THE TOXIC CHEMICAL ON-SITE AT ANY TIME DURING THE CALENDAR YEAR

4.1	☐ (Enter two-digit code from instruction package.)	

SECTION 5. QUANTITY OF THE TOXIC CHEMICAL ENTERING EACH ENVIRONMENTAL MEDIUM

			A. Total Release (pounds/year)(enter range from instructions or estimate)	B. Basis of estimate (enter code)	C. % From Stormwater
5.1	Fugitive or non-point air emissions	NA ☐			
5.2	Stack or point air emissions	NA ☐			
5.3	Discharges to receiving streams or water bodies (enter one name per box)				
	Stream or Water Body Name				
5.3.1					
5.3.2					
5.3.3					
5.4.1	Underground Injection on-site to Class I Wells	NA ☐			
5.4.2	Underground Injection on-site to Class II-V Wells	NA ☐			

If additional pages of Part II, Section 5.3 are attached, indicate the total number of pages in this box ☐ and indicate which Part II, Section 5.3 page this is, here ☐ (example: 1,2,3, etc.)

Range Codes: A = 1 - 10 pounds; B = 11 - 499 pounds; C = 500 - 999 pounds.

EPA FORM R
PART II. CHEMICAL-SPECIFIC INFORMATION (CONTINUED)

TRI FACILITY ID NUMBER

Toxic Chemical, Category, or Generic Name

SECTION 5. QUANTITY OF THE TOXIC CHEMICAL ENTERING EACH ENVIRONMENTAL MEDIUM

		NA	A. **Total Release** (pounds/year) (enter range code from instructions or estimate)	B. **Basis of Estimate** (enter code)
5.5	Disposal to land on-site			
5.5.1A	RCRA Subtitle C landfills	☐		
5.5.1B	Other landfills	☐		
5.5.2	Land treatment/application farming	☐		
5.5.3	Surface impoundment	☐		
5.5.4	Other disposal	☐		

SECTION 6. TRANSFERS OF THE TOXIC CHEMICAL IN WASTES TO OFF-SITE LOCATIONS

6.1 DISCHARGES TO PUBLICLY OWNED TREATMENT WORKS (POTWs)

6.1.A. Total Quantity Transferred to POTWs and Basis of Estimate

6.1.A.1. Total Transfers (pounds/year) (enter range code or estimate)	**6.1.A.2 Basis of Estimate** (enter code)

6.1.B. ___ POTW Name							
POTW Address							
City		State		County		Zip	
6.1.B. ___ POTW Name							
POTW Address							
City		State		County		Zip	

If additional pages of Part II, Section 6.1 are attached, indicate the total number of pages in this box ☐ and indicate which Part II, Section 6.1 page this is here ☐ (example: 1,2,3, etc.)

SECTION 6.2 TRANSFERS TO OTHER OFF-SITE LOCATIONS

6.2 ___OFF-SITE EPA IDENTIFICATION NUMBER (RCRA ID NO.)							
Off-Site Location Name							
Off-Site Address							
City		State		County		Zip	

Is location under control of reporting facility or parent company? ☐ **Yes** ☐ **No**

Range Codes: A = 1 - 10 pounds; B = 11 - 499 pounds; C = 500 - 999 pounds.

EPA FORM R
PART II. CHEMICAL-SPECIFIC INFORMATION (CONTINUED)

TRI FACILITY ID NUMBER

Toxic Chemical, Category, or Generic Name

SECTION 6. 2 TRANSFERS TO OTHER OFF-SITE LOCATIONS (continued)

A. Total Transfers (pounds/year) (enter range code or estimate)	B. Basis of Estimate (enter code)	C. Type of Waste Treatment/Disposal/ Recycling/Energy Recovery (enter code)
1.	1.	1.M
2.	2.	2.M
3.	3.	3.M
4.	4.	4.M

6.2 ___ OFF-SITE EPA IDENTIFICATION NUMBER (RCRA ID NO.)

Off-Site Location Name

Off-Site Address

City | State | County | Zip

Is location under control of reporting facility or parent company? ☐ **Yes** ☐ **No**

A. Total Transfers (pound/year) (enter range code or estimate)	B. Basis of Estimate (enter code)	C. Type of Waste Treatment/Disposal/ Recycling/Energy Recovery (enter code)
1.	1.	1.M
2.	2.	2.M
3.	3.	3.M
4.	4.	4.M

SECTION 7A. ON-SITE WASTE TREATMENT METHODS AND EFFICIENCY

☐ **Not Applicable (NA) - Check here if no on-site waste treatment is applied to any waste stream containing the toxic chemical or chemical category.**

a. General Waste Stream (enter code)	b. Waste Treatment Method(s) Sequence [enter 3-character code(s)]	c. Range of Influent Concentration	d. Waste Treatment Efficiency Estimate	e. Based on Operating Data?
7A.1a	7A.1b: 1 2 3 4 5 6 7 8	7A.1c	7A.1d	7A.1e
			%	Yes ☐ No ☐
7A.2a	7A.2b: 1 2 3 4 5 6 7 8	7A.2c	7A.2d	7A.2e
			%	Yes ☐ No ☐
7A.3a	7A.3b: 1 2 3 4 5 6 7 8	7A.3c	7A.3d	7A.3e
			%	Yes ☐ No ☐
7A.4a	7A.4b: 1 2 3 4 5 6 7 8	7A.4c	7A.4d	7A.4e
			%	Yes ☐ No ☐
7A.5a	7A.5b: 1 2 3 4 5 6 7 8	7A.5c	7A.5d	7A.5e
			%	Yes ☐ No ☐

If additional pages of Part II, Sections 6.2/7A are attached, indicate the total number of pages in this box ☐ and indicate which Part II, Sections 6.2/7A page this is, here. ☐ (example: 1.2.3. etc.)

Range Codes: A= 1-10 pounds; B=11- 499 pounds; C= 500 - 999 pounds.

EPA FORM R
PART II. CHEMICAL-SPECIFIC INFORMATION (CONTINUED)

TRI FACILITY ID NUMBER

Toxic Chemical, Category, or Generic Name

SECTION 7B. ON-SITE ENERGY RECOVERY PROCESSES

☐ **Not Applicable (NA) - Check here if no on-site energy recovery is applied to any waste stream containing the toxic chemical or chemical category.**

Energy Recovery Methods [enter 3-character code (s)]

1 ____ 2 ____ 3 ____ 4 ____

SECTION 7C. ON-SITE RECYCLING PROCESSES

☐ **Not applicable (NA) - Check here if no on-site recycling is applied to any waste stream containing the toxic chemical or chemical category.**

Recycling Methods [enter 3-character code(s)]

1 ____ 2 ____ 3 ____ 4 ____ 5 ____

6 ____ 7 ____ 8 ____ 9 ____ 10 ____

SECTION 8. SOURCE REDUCTION AND RECYCLING ACTIVITIES

	All quantity estimates can be reported using up to two significant figures.	**Column A** Prior Year (pounds/year)	**Column B** Current Reporting Year (pounds/year)	**Column C** Following Year (pounds/year)	**Column D** Second Following Year (pounds/year)
8.1	**Quantity released***				
8.2	**Quantity used for energy recovery on-site**				
8.3	**Quantity used for energy recovery off-site**				
8.4	**Quantity recycled on-site**				
8.5	**Quantity recycled off-site**				
8.6	**Quantity treated on-site**				
8.7	**Quantity treated off-site**				
8.8	**Quantity released to the environment as a result of remedial actions, catastrophic events, or one-time events not associated with production processes** (pounds/year)				
8.9	**Production ratio or activity index**				

8.10 **Did your facility engage in any source reduction activities for this chemical during the reporting year? If not, enter "NA" in Section 8.10.1 and answer Section 8.11.**

	Source Reduction Activities [enter code(s)]	**Methods to Identify Activity (enter codes)**		
8.10.1		a.	b.	c.
8.10.2		a.	b.	c.
8.10.3		a.	b.	c.
8.10.4		a.	b.	c.

8.11 **Is additional optional information on source reduction, recycling, or pollution control activities included with this report? (Check one box)** YES ☐ NO ☐

* Report releases pursuant to EPCRA Section 329(8) including "any spilling, leaking, pumping, pouring, emitting, emptying, discharging, injecting, escaping, leaching, dumping, or disposing into the environment." Do not include any quantity treated on-site or off-site.

Attachment C11-3: Excerpt from 40 CFR 355 Appendix A

Purpose: To demonstrate threshold planning quantities (TPQs) for extremely hazardous substances.

Instructions: Consult this list to determine threshold quantities for reporting hazardous materials to regulatory agencies.

Attachment C11-3: Excerpt from 40 CFR 355 Appendix A

Appendix A: The List of Extremely Hazardous Substances and Their Threshold Planning Quantities				
Appendix A to Part 355—The List of Extremely Hazardous Substances and Their Threshold Planning Quantities				
CAS Number	**Chemical Name**	**Notes**	**Reportable Quantity* (pounds)**	**Threshold Planning Quantity (pounds)**
75-86-5	Acetone Cyanohydrin		10	1,000
1752-30-3	Acetone Thiosemicarbazide		1,000	1,000/10,000
107-02-8	Acrolein		1	500
79-06-1	Acrylamide	1	5,000	1,000/10,000
107-13-1	Acrylonitrile	1	100	10,000
814-68-6	Acrylyl Chloride	h	100	100
111-69-3	Adiponitrile	1	1,000	1,000
116-06-3	Aldicarb	c	1	100/10,000
309-00-2	Aldrin		1	500/10,000
107-18-6	Allyl Alcohol		100	1,000
107-11-9	Allylamine		500	500
20859-73-8	Aluminum Phosphide	b	100	500
54-62-6	Aminopterin		500	500/10,000
78-53-5	Amiton		500	500
3734-97-2	Amiton Oxalate		100	100/10,000
7664-41-7	Ammonia	1	100	500
300-62-9	Amphetamine		1,000	1,000
62-53-3	Aniline	1	5,000	1,000
88-05-1	Aniline, 2, 4, 6-Trimethyl		500	500
7783-70-2	Antimony Pentafluoride		500	500
1397-94-0	Antimycin A	c	1,000	1,000/10,000
86-88-4	ANTU		100	500/10,000
1303-28-2	Arsenic Pentoxide		1	100/10,000
1327-53-3	Arsenous Oxide	h	1	100/10,000

Attachment C11-3: Excerpt from 40 CFR 355 Appendix A

CAS Number	Chemical Name	Notes	Reportable Quantity* (pounds)	Threshold Planning Quantity (pounds)
7784-34-1	Arsenous Trichloride		1	500
7784-42-1	Arsine		100	100
2642-71-9	Azinphos-Ethyl		100	100/10,000
86-50-0	Azinphos-Methyl		1	10/10,000
98-87-3	Benzal Chloride		5,000	500
98-16-8	Benzenamine, 3-(Trifluoromethyl)		500	500
100-14-1	Benzene, 1-(Chloromethyl)-4-Nitro		500	500/10,000
98-05-5	Benzenearsonic Acid		10	10/10,000
3615-21-2	Benzimidazole, 4, 5-Dichloro-2-(Trifluoromethyl)	g	500	500/10,000
98-07-7	Benzotrichloride		10	100
100-44-7	Benzyl Chloride		100	500
140-29-4	Benzyl Cyanide	h	500	500
15271-41-7	Bicyclo[2 2.1] Heptane-2-Carbonitrile, 5-Chloro-6-(Methylamino, Carbonyl, Oxy Imino,-1s-1-alpha, 2-beta, 4-alpha, 5-alpha, 6E)		500	500/10,000
534-07-6	Bis (Chloromethyl) Ketone		10	10/10,000
4044-65-9	Bitoscanate		500	500/10,000
10294-34-5	Boron Trichloride		500	500
7637-07-2	Boron Trifluoride		500	500
353-42-4	Boron Trifluoride Compound with Methyl Ether (1:1)		1,000	1,000
28772-56-7	Bromadiolone		100	100/10,000
7726-95-6	Bromine	1	500	500
1306-19-0	Cadmium Oxide		100	100/10,000
2223-93-0	Cadmium Stearate	c	1,000	1,000/10,000
7778-44-1	Calcium Arsenate		1	500/10,000
8001-35-2	Camphechlor		1	500/10,000
56-25-7	Cantharidin		100	100/10,000

Attachment C11-3: Excerpt from 40 CFR 355 Appendix A

CAS Number	Chemical Name	Notes	Reportable Quantity* (pounds)	Threshold Planning Quantity (pounds)
51-83-2	Carbachol Chloride		500	500/10,000
26419-73-8	Carbamic Acid, Methyl-, O-(2, 4-Dimethyl-1, 3-Dithiolan-2-yl Methylene Amino)	d	1	100/10,000
1563-66-2	Carbofuran		10	10/10,000
75-15-0	Carbon Disulfide	1	100	10,000
786-19-6	Carbophenothion		500	500
57-74-9	Chlordane		1	1,000
470-90-6	Chlorfenvinfos		500	500
7782-50-5	Chlorine		10	100
24934-91-6	Chlormephos		500	500
999-81-5	Chlormequat Chloride	h	100	100/10,000
79-11-8	Chloroacetic Acid		100	100/10,000
107-07-3	Chloroethanol		500	500
627-11-2	Chloroethyl Chloroformate		1,000	1,000
67-66-3	Chloroform	1	10	10,000
542-88-1	Chloromethyl Ether	h	10	100
107-30-2	Chloromethyl Methyl Ether	c	10	100
3691-35-8	Chlorophacinone		100	100/10,000
1982-47-4	Chloroxuron		500	500/10,000

*Only the statutory or final RQ is shown. For more information, see 40 CFR Table 302.4.

Notes:

a. This chemical does not meet acute toxicity criteria. Its TPQ is set at 10,000 pounds.
b. This material is a reactive solid. The TPQ does not default to 10,000 pounds for nonpowder, nonmolten, nonsolution form.
c. The calculated TPQ changed after technical review as described in the technical support document.
d. Indicates that the RQ is subject to change when the assessment of potential carcinogenicity and/or other toxicity is completed.
e. Statutory reportable quantity for purposes of notification under SARA section 304(a)(2).
f. Reserved.
g. New chemicals added that were not part of the original list of 402 substances.
h. Revised TPQ based on new or re-evaluated toxicity data.
j. TPQ is revised to its calculated value and does not change due to technical review as in proposed rule.
k. The TPQ was revised after proposal due to calculation error.
l. Chemicals on the original list that do not meet toxicity criteria but because of their high production volume and recognized toxicity are considered chemicals of concern ("Other Chemicals")

1.0 Introduction

This chapter discusses wastewater regulations that may apply to an EPA laboratory. During both normal and experimental operations, a variety of wastewater will be generated. This wastewater can be a source of pollution if it contains contaminants (e.g., metals, radionuclides) or exhibits potentially hazardous properties (e.g., acidity, temperature). Therefore, an EPA laboratory should characterize its wastewater before discharging it directly into a navigable waterway or into a publicly-owned treatment works (POTW), to determine whether any restrictions on its discharge apply. The sections in this chapter address the federal regulations that govern wastewater discharges.

EPA Program Requirements

To ensure that it meets the applicable federal regulatory requirements, an EPA laboratory must consider whether, based on its design and operation, it is subject to the following requirements for water pollution control:

- The National Pollutant Discharge Elimination System (NPDES) Program for wastewater discharges and point-source discharges into a navigable waterway
- A pretreatment/POTW program for point-source discharges to a POTW
- Operating and maintaining wastewater systems
- Monitoring wastewater discharges for prohibited pollutants
- Reporting requirements

Program Administration

To effectively manage a wastewater program, an EPA laboratory should assign responsibility for the following items, as applicable:

Management of Change

- Assessing the regulatory implications of changes in laboratory design and/or operation
- Tracking changes to regulatory requirements that could affect the laboratory

Permitting and Permit Requirements

- Ensuring that wastewater discharges are permitted as required by governing regulatory requirements
- Ensuring compliance with the requirements established in the laboratory's wastewater discharge permit(s)

Wastewater System Maintenance

- Ensuring that appropriate wastewater system measures (e.g., treatment and/or control) are in place, and that they are operating effectively

Wastewater Discharge Monitoring

- Monitoring quantities of pollutants in wastewater discharges

Recordkeeping and Reporting

- Establishing and maintaining a recordkeeping system for information required by the governing regulations and/or wastewater discharge permit(s)

- Preparing and submitting, as required, notifications and report(s) to the EPA

2.0 Management Systems

An EPA laboratory should assess the actual and potential impacts that its wastewater discharges have on the environment. The release of a pollutant in an amount, concentration, level, or rate of release that causes, or may cause, an exceedance of established wastewater discharge limit and/or a significant adverse effect on the environment must not be allowed. To completely understand and effectively manage its wastewater program, an EPA laboratory should consider implementing management systems as described in the following sections.

2.1 Wastewater Discharge Inventory

EPA laboratories should maintain a comprehensive listing of wastewater discharges that includes the sources and locations of the discharges, as well as analytical data characterizing the nature and volume of the discharges. Consideration should be given to the following:

- Points where normal or unusual discharges of wastewater or contaminated surface water leave or may leave the boundary of the laboratory (e.g., floor and sink drains, discharge outfall pipes)

- Manufacturing operations, domestic wastewater, noncontact cooling water, etc., that contribute to the laboratory's effluent

- Contaminant contributions to the laboratory's effluent, such as manufacturing/storage area runoff, dredge and fill solids, drainage water, leachates, septic tank discharge areas, wastewater treatment plant effluent, lagoons, surface impoundments, and process wastewater

- Points where flow from adjacent property or surface water runoff may affect the quality of the laboratory's effluent

  [Note: An EPA laboratory should also maintain sufficient documentation (i.e., process or equipment information) to help determine the applicability of wastewater discharge permit requirements.]

2.2 Programs and Practices

EPA laboratories should design and implement programs and practices for controlling and minimizing wastewater discharges during the full range of operations. Where feasible, the laboratory should consider establishing a program to apply appropriate technology to minimize or reduce the effects from discharges that cannot otherwise be eliminated (e.g., the installation of acid neutralization chip tanks, contaminant recovery units, collection sumps).

2.3 Wastewater Discharge Prevention

EPA laboratories should establish a program to reduce or eliminate wastewater discharges from its operations and/or consider discharge prevention objectives in the design of new or modified facilities and processes.

3.0 Regulatory Applicability

Depending on its design and operations, an EPA laboratory that has wastewater or stormwater discharges may be subject to the permit programs as described in the following sections. Many states have wastewater discharge legislation and regulations that require permitting similar to the NPDES Program (i.e., these states have been delegated authority by the EPA to administer the NPDES Program). However, this is not always the case. Some states have chosen not to administer the NPDES Program, and instead issue a state permit; however, this does not preclude participation in the federal NPDES Program. As a result, an EPA laboratory located in such a state would have two permits. Local agencies may also develop enforceable limit on wastewater discharges to POTWs for items such as pH, temperature, and concentrations of various contaminants.

3.1 NPDES

NPDES is the primary regulatory program governing wastewater discharges. The fundamental concept of this program is that a facility may not discharge pollutants to the navigable waters of the United States without a permit. The NPDES Program regulates "point source" wastewater discharges from various sources directly into a navigable waterway, including wastewaters from industrial and commercial sources and POTWs. To obtain an NPDES permit, an EPA laboratory must complete a permit application.

3.2 Pretreatment/POTW

Industrial and commercial facilities and POTWs that receive off-site wastewater are usually required to develop and implement a pretreatment program that regulates the characteristics of the influent that they receive. It is likely that an EPA laboratory that sends out any contaminants in lab packs, and/or discharges directly to the sanitary sewer system, would be subject to these requirements.

3.3 Stormwater

Under 40 CFR 122.26, the EPA requires NPDES permits for specific types of stormwater discharges. Those categories that could potentially apply to an EPA laboratory include discharges associated with an "industrial activity" as defined in the governing regulations; discharges having NPDES permits issued as of February 1987; and any other discharges deemed by the EPA to "contribute to a violation of a water quality standard or is a significant contributor of pollutants to water of the United States." Refer to section 8.0 of this chapter for more information on stormwater.

4.0 Permit and Program Requirements

An NPDES permit is required if the laboratory discharges treated or untreated wastewater into a navigable waterway (i.e., surface water). If an

EPA laboratory discharges treated or untreated wastewater to a POTW, it must receive approval from the POTW under the POTW's Pretreatment Program.

To obtain a permit, an EPA laboratory must prepare and submit an application to the EPA and/or state environmental agency that contains information pertaining to the laboratory's discharges, sources of contaminants, flow rates, treatment processes, etc. The responsible agency will then act on the application by preparing a draft permit for public comment prior to issuing the final permit.

In general, NPDES permits contain the specific effluent limits designated by the regulatory agency as necessary to protect surface water quality (e.g., pH, temperature, flow, oil and grease, ammonia, biological oxygen demand [BOD], total suspended solids [TSS]). However, an EPA laboratory should also review the "Effluent Guidelines" established in 40 CFR 403 through 471 to identify possible applicable requirements not explicitly identified in the laboratory's permit(s). NPDES permits typically include the following general conditions (refer to 40 CFR 122.41):

- Operation and maintenance
- Monitoring and recordkeeping
- Planned changes
- Noncompliance
- Bypass condition
- Upset condition

An EPA laboratory that is covered by an NPDES permit, or equivalent, must comply with all of the conditions of the permit. Any permit noncompliance constitutes a violation of the Clean Water Act, and may result in an enforcement action; termination, revocation, and reissuance of the permit; modification of the permit; and/or denial of a permit renewal application.

4.1 Operation and Maintenance

An EPA laboratory's systems of treatment and/or control that are necessary to achieve compliance with the conditions of its permit must be properly operated and maintained. Proper operation and maintenance includes adequate laboratory control, appropriate quality assurance procedures, and sufficiently trained personnel. The operation and maintenance provision also requires the operation of backup or auxiliary facilities (or similar systems that are installed by a permittee) only when the operation is necessary to achieve compliance.

4.2 Monitoring and Recordkeeping

All samples and measurements that are taken for the purpose of monitoring, in accordance with established analytical procedures, must be representative of the monitored activity.

4.3 Planned Changes

An EPA laboratory should, as soon as possible, notify the regulatory agency of any planned physical alterations or additions to the laboratory when the alteration or addition:

- Meets one of the criteria for determining whether a laboratory is considered a new source under 40 CFR 122.29(b)

- Could significantly change the nature or increase the quantity of pollutants discharged

- Results in a significant change in sludge use or disposal practices, and such alteration, addition, or change may justify the application of permit conditions that are different or absent from those conditions in the existing permit

4.4 Noncompliance

An EPA laboratory representative must report all instances of noncompliance to the regulatory agency within 24 hours of becoming aware of the noncompliance. In some cases, this report may be deferred until the time that the laboratory's monitoring report is submitted. Refer to section 6.0 of this chapter for a description of the reporting process.

4.5 Bypass Condition

Bypass of an EPA laboratory's wastewater treatment equipment may only occur if it does not cause effluent limits to be exceeded, and only if it is for essential maintenance to ensure efficient operation of the system. An EPA laboratory must communicate anticipated bypasses to the regulatory agency prior to such an event, and for unanticipated bypasses, the laboratory must notify the agency within 24 hours of the event.

4.6 Upset Condition

An upset condition constitutes an affirmative defense to an action brought for noncompliance with technology-based permit effluent limitations if the following three conditions are met:

- The EPA laboratory can identify the cause of the upset.
- At the time of the event, the system was being properly operated.
- Notice of the upset was communicated to the regulatory agency within 24 hours of the event.

5.0 Monitoring

NPDES permits, and many Pretreatment/POTW Programs, require monitoring of wastewater effluent. Depending on the analytical parameter and the complexity of the effluent, monitoring samples may be either grab samples or composite samples. Grab samples are instantaneous samples usually taken by dipping a sample container or bucket into the effluent stream. Composite samples are taken over a specified time (usually 24 hours). This is usually performed by an automated sampler, although it may also be accomplished manually.

An EPA laboratory must use the test procedures established in 40 CFR 136 when sampling and analyzing wastewater effluent. In addition, the current edition of the *Standard Methods for the Examination of Water and Wastewater* is the most commonly accepted methodology for sampling and analyzing wastewater.

If any pollutant is monitored more frequently than required by the permit, test procedures approved under 40 CFR 136 are used. In the case of sludge use or disposal, test procedures approved

under 40 CFR 136, or as specified in the permit, are used. The results of this monitoring must be included in the calculation and reporting of the data submitted in the discharge monitoring report or sludge reporting form specified by the regulatory agency.

If an EPA laboratory's permit requires that samples be taken on a monthly basis, and the laboratory elects to sample on a more frequent basis (i.e., weekly), the results of all of the samples must be reported if they were:

- Representative of the monitored activity
- Obtained using an approved standard method
- Analyzed using established analytical procedures

6.0 Reporting

Reporting under the NPDES regulations can be divided into two categories: routine and nonroutine. Each are discussed in the following sections.

6.1 Routine Reporting

For NPDES permits, a monthly discharge monitoring report (DMR) that documents monitoring results and demonstrates the EPA Laboratory's level of compliance with effluent limitations is usually required by the regulatory agency. DMRs must be signed by an officer of the company or his/her duly authorized representative. Routine reporting can also be specified by the POTW as part of the pretreatment program authorization.

6.2 Nonroutine Reporting

Nonroutine reporting is required whenever an event causes an exceedance of effluent limits, including bypasses, upsets, pollutant exceedances, or other emergency events. Any noncompliance event that may endanger human health or the environment shall be orally reported to the regulatory agency within 24 hours from the time the EPA laboratory becomes aware of the event.

The EPA laboratory must also provide a written submission to the regulatory agency within five days of the time the event is identified. The written submission must contain:

- A description of the noncompliance and its cause
- The period of noncompliance, including the exact dates and times
- The anticipated duration of the event (if the noncompliance had not yet been corrected)
- The steps taken or planned to reduce, eliminate, and prevent reoccurrence of the noncompliance

[Note: The regulatory agency may waive the written report requirement on a case-by-case basis.]

7.0 Recordkeeping

Monitoring records must include the following:

- The date, exact place, and time of sampling or measurements
- The individual(s) who performed the sampling or measurements
- The date(s) that analyses were performed

- The individual(s) who performed the analyses
- The analytical techniques or methods used
- The results of such analyses

Records of all monitoring must be maintained for a period of at least three years from the date of the sample, measurement, report, or application (e.g., calibration and maintenance records and strip chart recordings for continuous monitoring instrumentation, copies of reports required by the wastewater discharge permit, and records of data used to complete the permit application).

[Note: Records of any required monitoring information related to sewage sludge use and disposal must be retained for a period of at least five years (or longer as required by 40 CFR 503).]

8.0 Stormwater

At EPA laboratories there may be spill containment barriers around outdoor tanks or storage areas. These containment barriers can collect rainwater. Because this water can pick up contaminants, its discharge must be closely monitored.

The discharge of stormwater from certain industrial activities is regulated by the EPA as part of the NPDES Program under 40 CFR 122.26.

Each laboratory component or system must be examined for its potential for causing a release of pollutants due to equipment failure (e.g., a tank overflow or leakage), improper operation, or natural phenomena (e.g., rain or snowfall, etc.).

Where experience indicates a reasonable potential for such a release, the plan should predict the direction, rate of flow, and total quantity of the pollutants that could be released from the facility as a result of each condition or circumstance.

8.1 Applicability

The EPA has delegated authority for administration of the stormwater program to the states. Depending on how stormwater is managed at an EPA laboratory, the laboratory may be subject to an individual permit or a general permit, or it may not be required to obtain a permit.

Laboratories that discharge stormwater associated with industrial activity are required to:

- Apply for an individual permit
- Apply for a permit through a group application
- Seek coverage under a promulgated general permit

8.2 Permit Conditions

Individual and general permits typically contain provisions related to operation and maintenance of the stormwater management system. Monitoring requirements may also be imposed with sampling required during certain storm events. An EPA laboratory may be required to prepare and implement a Best Management Practices (BMP) Plan, otherwise known as a Stormwater Pollution Prevention Plan (SWP^3), to reduce its potential to discharge pollut-

ants to stormwater. This plan may be a stand-alone plan, or integrated into an EPA laboratory's Spill Prevention Control and Countermeasures (SPCC) Plan. Refer to Attachment C12-1 for an example of the BMP requirements imposed by a state in an NPDES permit that it issued.

Attachment C12-1: Best Management Practices for NPDES Permitting

Purpose: To serve as an example of Best Management Practices that may be imposed on an EPA laboratory.

Instructions: Refer to the example to make improvements to the laboratory's current permit management system.

General Conditions

1. Applicability

These conditions apply to all permittees who use, manufacture, store, handle, or discharge any pollutant listed as toxic under Section 307(a)(1) of the Clean Water Act; oil, as defined in Section 311(a)(1) of the Act; and any pollutant listed as hazardous under Section 311 of the Act, and who have ancillary manufacturing operations that could result in the release of a hazardous substance, pollutant, or contaminant (hereafter referred to as the "BMP pollutants") in a reportable quantity; or an environmental emergency. These operations include material storage areas; plant site runoff; in-plant transfer, process, and material handling areas; loading and unloading operations; and sludge and waste disposal areas.

2. BMP Plan

The permittee shall maintain a Best Management Practices (BMP) plan that prevents, or minimizes the potential for, the release of BMP pollutants from ancillary activities through plant site runoff; spillage or leads; sludge or waste disposal; or drainage from raw material storage.

3. Implementation

The plan shall continue in effect and shall be modified as necessary.

4. General Requirements

The BMP plan shall:

a. Be documented in narrative form, and shall include any necessary plot plans, drawings, or maps.

b. Establish specific objectives for the control of toxic and hazardous pollutants.

    1. Each facility component or system shall be examined for its potential for causing a release of BMP pollutants due to equipment failure, improper operation, natural phenomena such as rain or snowfall, etc.

2. Where experience indicates a reasonable potential for equipment failure (e.g., a tank overflow or leakage), natural condition (e.g., precipitation), or other circumstances that could result in a release of BMP pollutants, the plan should include a prediction of the direction, rate of flow, and total quantity of the pollutants that could be released from the facility as result of each condition or circumstance.

c. Establish specific best management practices to meet the objectives identified under paragraph b of this section, addressing each component or system capable of causing a release of BMP pollutants.

d. Include any special conditions.

e. Be reviewed by engineering staff and the laboratory manager.

5. Specific Requirements

The plan shall be consistent with the general guidance contained in the publication entitled "NPDES Best Management Practices Guidance Document" and must include the following baseline BMPs as a minimum.

a. BMP committee
b. Reporting of BMP incidents
c. Risk identification and assessment
d. Employee training
e. Inspections and records
f. Preventive maintenance
g. Good housekeeping
h. Materials compatibility
i. Security
j. Materials inventory

6. SPCC Plans

The BMP plan may reflect requirements for Spill Prevention Control and Countermeasure (SPCC) plans under Section 311 of the Act and 40 CFR Part 151, and may incorporate any part of such plans into the BMP plan by reference.

7. Hazardous Waste Management

The permittee shall ensure the proper management of solids and hazardous waste in accordance with the regulations promulgated under the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1978 (RCRA) (40 U.S.C. 6901 et seq). Management practices required under RCRA regulations shall be referenced in the BMP plan.

8. Documentation

The permittee shall maintain a copy of the BMP plan at the facility and shall make the plan available to representatives of the Division of Water upon request. Copies of modified BMP Plans shall be submitted within thirty (30) days of completion.

9. BMP Plan Modification

The permittee shall amend the BMP plan whenever there is a change in the facility (or change in the operation of the facility) that materially increases the potential for the ancillary activities to result in the release of "BMP pollutants."

10. Modification for Ineffectiveness

If the BMP plan proves to be ineffective in achieving the general objective of preventing the release of BMP pollutants then the specific objectives and requirements under Paragraphs b and c of Section 4, the permit and/or the BMP plan shall be subject to modification to incorporate revised BMP requirements. If, at any time following the issuance of this permit, the BMP plan is found to be inadequate pursuant to a state or federal site inspection or plan review, the plan shall be modified to incorporate such changes necessary to resolve the concerns.

1.0 Introduction

The EPA's regulations on oil pollution prevention became effective on December 11, 1973, and were designed to prevent oil pollution of the waters of the United States. One mechanism established for accomplishing this is the Spill Prevention Control and Countermeasure (SPCC) Plan. The regulations that govern the preparation, issuance, amendment, and implementation of an SPCC plan are contained in 40 CFR 112. The federal oil pollution prevention regulations focus on *prevention* and *planning* specifically related to oil, and do not address or require the preparation of a plan for chemicals or hazardous substances. However, an EPA laboratory should consider expanding the scope of its SPCC Plan to include materials other than oil.

[Note: In some cases, an EPA laboratory may be required to prepare and implement a Best Management Practices (BMP) Plan, otherwise known as a Stormwater Pollution Prevention Plan, to reduce its potential to discharge certain Clean Water Act pollutants to stormwater. This plan may be a stand-alone plan, or integrated into an EPA Laboratory's SPCC Plan. Refer to Chapter C12 of this manual for more information.]

EPA Program Requirements

To ensure that it meets the applicable federal regulatory requirements, an EPA laboratory must consider whether, based on its design and operation, it is subject to the following requirements for oil pollution prevention:

- Preparing, maintaining, and implementing an SPCC Plan
- Training employees on the pollution control laws and regulations that apply to the laboratory and the proper operation and maintenance of equipment to prevent discharges of oil

Program Administration

To effectively manage an SPCC program, an EPA laboratory should assign responsibility for the following items, as applicable:

- Determining whether the laboratory is subject to SPCC Plan requirements
- Preparing and issuing an SPCC Plan
- Implementing the requirements contained in the SPCC Plan (e.g., containment, inspections, training)
- Amending the SPCC Plan as required (e.g., whenever there is a change to the laboratory design, construction, operation, or maintenance that may affect the laboratory's oil discharge potential; if the laboratory experiences two spill events in any 12-month period; or if the laboratory has a single spill event that results in the discharge of more than 1,000 gallons)
- Reviewing, revising, and recertifying the SPCC Plan every three years

2.0 Applicability of SPCC Plan Requirements

An EPA laboratory that meets the following conditions is required to prepare and implement an SPCC Plan:

Condition #1: Storage Capacity

- More than 1,320 gallons of oil above ground, or
- Oil in a single container with a capacity greater than 660 gallons above ground, or
- More than 42,000 gallons below ground

AND

Condition #2: Location

- Located in an area where there is a potential to discharge oil into a navigable waterway (as defined in the Clean Water Act)

[Note: This is determined based on the location of the laboratory relative to a navigable waterway, and does consider systems used to prevent releases (e.g., secondary containment, equipment, etc.).]

An EPA laboratory that *does not meet* both of the above conditions *is not required* to prepare and implement an SPCC Plan.

There are two items that an EPA laboratory should take into consideration when making an SPCC Plan applicability determination. The first is the definition of "oil" - which includes a wide variety of substances, including:

- Crude oils
- Transformer oils
- Vegetable oils
- Lacquer-base paints and varnishes

Refer to Attachment C13-1 for EPA Guidance on the Clean Water Act Definition of Oil.

The second consideration when making an SPCC plan is related to the total aboveground storage capacity of a laboratory which includes containers, drums, tanks, etc., that contain oils. Based on this definition, it does not take that many 55-gallon drums to exceed the threshold. Further, the applicability threshold is based on the potential to contain, and not the actual quantity of material contained. So, even if a laboratory routinely stored only 10 gallons of oil in a 55-gallon drum, for the purpose of the applicability determination, this drum would still be considered to contribute 55 gallons to the total quantity of oil stored. As such, it may be relatively easy for some EPA laboratories to exceed 1,320 gallons of oil stored.

3.0 SPCC Plan

This section addresses the regulatory requirements that govern the preparation, implementation, and amendment of an SPCC Plan.

3.1 SPCC Plan Preparation and Implementation

An EPA laboratory that is subject to SPCC Plan requirements must prepare this plan within six months after the date the laboratory begins operations. The plan must be reviewed and certified by a registered professional engineer. This certification attests that the SPCC Plan has been prepared in accordance with good engineering practices. An EPA laboratory must implement its SPCC Plan *as soon as possible, but not later than one year* after the laboratory begins operations.

[Note: In some cases, the EPA may authorize an extension of time for the preparation and full implementation of an SPCC Plan; this extension must be specifically requested by an EPA laboratory.]

3.2 SPCC Plan Contents

The SPCC Plan must be a carefully thought-out plan, prepared in accordance with good engineering practices, and have the full approval of management including commitment of the necessary resources. If the plan calls for additional facilities, procedures, methods, or equipment not yet fully operational, these items should be discussed—including the details of installation and operational start-up.

An SPCC Plan must include a discussion of the EPA laboratory's conformance with the following items:

- Spill event history
- Failure analysis
- Containment and diversionary structures

In addition, an SPCC Plan should include a discussion of other applicable regulatory guidelines noted in 40 CFR 112.7(e). Refer to section 3.2.4 of this chapter for more information. Finally, an SPCC Plan must address requirements relative to:

- Inspections
- Recordkeeping
- Security
- Training

These requirements are discussed in sections 3.2.5 through 3.2.7 of this chapter.

Refer to Attachment C13-2 for an example of a table of contents for an SPCC Plan that addresses regulatory requirements.

An EPA laboratory should be aware of the fact that the implementation of an SPCC Plan is a regulatory requirement. That is, any "self-imposed" programs, procedures, practices, etc., that are set forth in the laboratory's SPCC Plan must be fully implemented, otherwise the laboratory is technically not in compliance with the requirement to implement its plan (i.e., 40 CFR 112.3).

3.2.1 Spill Event History

An EPA laboratory that has experienced one or more spill events within 12 months prior to the effective date of 40 CFR 112 should include a written description of each spill, the corrective action taken, and plans for preventing recurrence.

A spill event is a discharge of oil into or upon the navigable waters of the United States or adjoining shorelines in harmful quantities, as defined at 40 CFR Part 110 (e.g., a release that causes a sheen on water).

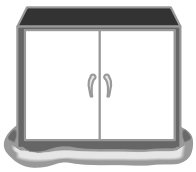
3.2.2 Failure Analysis

Where experience indicates a reasonable potential for equipment failure (such as tank overflow, rupture, or leakage), the plan should include a prediction of the direction, rate of flow, and total quantity of oil that could be discharged from the laboratory as a result of each type of major failure. For an EPA laboratory, consideration should be given to storage tanks and/or drum storage areas.

3.2.3 Containment and Diversionary Structures

Appropriate containment and/or diversionary structures, or equipment to prevent discharged oil from reaching a navigable waterway, should be provided. One of the following preventive systems or its equivalent should be used as a minimum:

- Dikes, beams, or retaining walls sufficiently impervious to contain spilled oil
- Culverting, gutters, or other drainage systems
- Sorbent materials
- Curbing, drip pans
- Sumps or collection systems
- Spill diversion or retention ponds



3.2.4 Other Applicable Guidelines

In addition to the items noted in sections 3.2.1 through 3.2.3, the SPCC Plan should include a complete discussion of compliance with the applicable guidelines noted in 40 CFR 112.7(e). These guidelines address the following areas that may apply to an EPA laboratory:

- Facility drainage
- Bulk aboveground and underground storage tanks (Refer to Chapter C16 for an overview of the requirements applicable to underground storage tanks.)
- Facility transfer operations, pumping, and in-plant process
- Tank car and tank truck loading/ unloading procedures

The plan should also include a complete discussion of compliance with other effective spill prevention and containment procedures, or if more stringent, with state rules, regulations and guidelines. Refer to section 3.4 for a description of state spill prevention and control programs.

3.2.5 Inspection Procedures and Recordkeeping Requirements

Inspections required by 40 CFR 112.7 (i.e., bulk storage tank integrity inspections, stormwater drainage inspections) should be in accordance with written procedures developed by the EPA laboratory. These procedures, and a record of the inspections, signed by the appropriate supervisor or inspector, should be made part of the SPCC Plan and maintained for a period of three years.

Bulk Storage Tank Integrity

Aboveground tanks should be subject to periodic integrity testing, taking into account tank design (floating roof, etc.), and using such techniques as hydrostatic testing, visual inspection, or a system of non-destructive shell thickness testing. Comparison records should be kept where

appropriate, and tank supports and foundations should be included in these inspections. The outside of the tank should frequently be observed by operating personnel for signs of deterioration, leaks which might cause a spill, or accumulation of oil inside diked areas.

Drainage of Rainwater from Containment Dikes

Drainage of rainwater from a diked area into a storm drain or an effluent discharge that empties into an open water course, lake, or pond may be acceptable if:

- The bypass valve is normally sealed closed
- Inspection of the rainwater runoff ensures that complies with applicable water quality standards and will not cause a harmful discharge as defined in 40 CFR Part 110
- The bypass valve is opened, and resealed following drainage under responsible supervision
- Adequate records are kept of such events

3.2.6 Visual Examinations

An EPA laboratory with aboveground valves and pipelines should subject this equipment to regular examinations. The general condition of items should be assessed, such as:

- Flange joints
- Expansion joints
- Valve glands and bodies
- Catch pans
- Pipeline supports
- Locking of valves
- Metal surfaces

In addition, periodic pressure testing may be warranted for piping in areas where facility drainage is such that a failure might lead to a spill event.

3.2.7 Security and Lighting

An EPA laboratory that handles, processes, and stores oil should be fully fenced, and entrance gates should be locked and/or guarded when the laboratory is unattended. If applicable:

- Master flow and drain valves and any other valves that will permit direct outward flow of the tank's contents to the surface should be securely locked in the closed position when in non-operating or standby status.
- The starter control on all oil pumps should be locked in the off position or located at a site accessible only to authorized personnel when the pumps are in a non-operating or standby status.
- The loading/unloading connections of oil pipelines should be securely capped or blank-flanged when not in service or standby service for an extended time. This security practice should also apply to pipelines that are emptied of liquid either by draining or by inert gas pressure.

In addition, lighting should be commensurate with the type and location of the EPA laboratory. Consideration should be given to:

- Discovery of spills occurring during hours of darkness, both by laboratory personnel, if present, and by others (the general public, local police, etc.)

- Prevention of spills occurring through acts of vandalism

3.2.8 Training

An EPA laboratory is responsible for properly instructing its personnel in applicable pollution control laws, rules and regulations and the operation and maintenance of equipment to prevent the discharges of oil. In that regard, the laboratory should have a designated person who is accountable for oil spill prevention and who reports to line management. In addition, the laboratory should schedule and conduct spill-prevention briefings for its operating personnel at intervals frequent enough to ensure adequate understanding of the laboratory's SPCC Plan. Such briefings should highlight and describe:

- Known spill events or failures

- Malfunctioning components

- Recently developed precautionary measures (e.g., floor drain covers to prevent spills from entering a sewer system)

Refer to Chapter C3 of this manual for additional information on training.

Scenario #1—Performance-Based

An amendment to the plan is required whenever a laboratory has discharged more than 1,000 gallons of oil into or upon the navigable waters of the United States or adjoining shorelines in a single event, or if a laboratory has experienced two or more spill events within any 12-month period. Within 60 days of such an event(s), the EPA laboratory must submit to the EPA a report that contains the following information:

- Name of the laboratory
- Name(s) of the owner or operator of the laboratory
- Location of the laboratory
- Date and year of initial laboratory operation
- Maximum storage or handling capacity of the laboratory and normal daily throughput
- Description of the laboratory, including maps, flow diagrams, and topographical maps
- A complete copy of the SPCC Plan with any amendments
- The cause(s) of such spill, including a failure analysis of the system(s) or subsystem(s) in which the failure occurred
- The corrective actions and/or countermeasures taken, including an adequate description of equipment repairs and/or replacements
- Additional preventive measures taken or contemplated to minimize the possibility of recurrence
- Such other information as the Regional Administrator may reasonably require pertinent to the Plan or spill event

Upon receipt of this information, the EPA may require the laboratory to amend its SPCC Plan.

Scenario #2—Design-Based

An amendment to the plan is required whenever there is a change in laboratory design, construction, operation, or maintenance that affects the laboratory's potential to discharge into or upon the navigable waters of the United States or adjoining shorelines. Such an amendment shall be fully *implemented as soon as possible, but not later than six months* after such change occurs.

This type of amendment must be reviewed and certified by a Registered Professional Engineer.

OR

Scenario #3—Three-Year Review

An amendment to the plan is required at least once every three years from the date the EPA laboratory becomes subject to the SPCC Plan regulations. As a result of this review and evaluation, the laboratory shall amend its SPCC Plan *within six months* of the review to include more effective prevention and control technology if:

- Such technology will significantly reduce the likelihood of a spill event from the laboratory
- Such technology has been field proven (i.e., demonstrated) at the time of the review

3.3 SPCC Plan Amendments

There are three main reasons why an SPCC Plan would be amended. Each of these "scenarios" is discussed in the following sections.

3.4 State Spill Prevention and Control Programs

The federal oil pollution prevention regulations provide for the preparation and implementation of an SPCC Plan in accordance with 40 CFR 112.7. However, an SPCC Plan should also be designed to complement existing laws, regulations, rules, standards, policies and procedures pertaining to:

- Safety standards
- Fire prevention
- Pollution prevention

Some states have developed overlapping and/or supplementary programs for spill prevention and control, secondary containment standards, inspection requirements, etc. The following are examples of the different types of regulatory programs that have been developed.

Spill Prevention and Control Plan Requirements

Supplement federal SPCC Plan requirements. Examples include:

- The Alaska Oil and Hazardous Substances Pollution Control requirements for bulk storage tanks with capacities greater than 10,000 gallons
- The Michigan Pollution Incident Prevention Plan
- The Minnesota Prevention and Response Plan
- The Pennsylvania Storage Tank and Spill Prevention Act

Tank Inspection Program Requirements
Prescribe detailed inspection criteria and/or reporting practices. Examples include:

- New York State Code of Rules and Regulations: monthly inspection requirements
- Rhode Island Oil Pollution Control Regulations: inspection report with annual submission requirements

Fire Prevention Standards
That govern secondary containment requirements for storage tanks containing flammable liquids. Examples include:

- New York City Fire Law Handbook
- Commonwealth of Pennsylvania Flammable & Combustible Liquids Handbook
- NFPA 30 Flammable and Combustible Liquids Code

Release-Reporting Requirements
That impose more stringent definitions of oil spills releases that have to be reported. Examples include:

- California Health and Safety Code requirements pertaining to the immediate reporting of a release of one barrel or more of petroleum to land

- Barclays California Code of Regulations

- State of Texas Oil and Hazardous Substances Spill Contingency Plan requirements pertaining to the immediate reporting of releases of harmful quantities of oil and hazardous substances

- Texas Administrative Code requirements pertaining to releases of 25 gallons or more of petroleum products and used oil

An EPA laboratory should review its state environmental regulatory program to determine whether there are additional requirements that pertain to it, and as indicated in section 3.2.4, these requirements should be reflected in the laboratory's SPCC Plan.

Attachment C13-1: Guidance on Clean Water Act Definition of Oil

Purpose: To provide a reference list of materials considered "oil" under the definition of oil in the Clean Water Act.

Instructions: Refer to this list when quantifying the oil present in the laboratory.

Attachment C13-2: Sample SPCC Plan Table of Contents

Oil of any Kind, in any Form

Oil

Cutting Oils
Transformer Oils
#2, #5 Fuel Oils, Bunker Fuel
Mix of Benzene, Toluene, and Xylene
Jet Fuels (JP-4, etc.)
Kerosene
Diesel Fuel
Gasoline
Motor Oils and Lubricating Oils
Animal and Vegetable Fats/Oils:
Whale Oil
Coconut Oil
Corn Oil
Tallow
Meat Rendering
Fish Oil
Tung Oil
Linseed Oil
Cottonseed Oil
Fuel Oil Sludge
Waste Oil
Oil Mixtures
Paraffin Wax
Asphalts
Tars (Petroleum)
Crude Oils
Naphtha
Mineral Spirits
Refinery Petroleum Waste
Lacquer-Base Paints/Varnishes
High-Temp Heating Oils (Dowthern, Therminol, etc.)

Not an Oil*

Toluene
Molasses
Plating Waste
Stearic Acid
Cresol
Hexanol
Methyl Mercury
DDT
Natural Gas Condensate
Naphthalene
Phenols
Toxaphene
Butanol
Ethanol
Methanol
TBA, MTBE (Gasoline Additives)
Benzene
Ketones
Acetone
Propanol
Glycol
Ethylene
Ethylene/Peopylene Glycol (Antifreeze)
Coal Tar

* The following conditions will apply if the material is an oil:

1. It is an isomer. An isomer is when a compound is identical to another compound in its formula but different in its molecular arrangement. An example is xylene, which has 3 isomers; ortho-xylene, meta-xylene, and para-xylene. The formula $C_8H_4(CH_3)_2$ is the same for all of these isomers. The difference in appearance is due to the different placement of the methyl groups on the benzene ring.

2. Secondly, by itself, the isomer is a non-oil; however, when combined with 3 or more in a homologous series, it becomes an oil. Homologous series is a series of compounds where each successive member has one or more CH_2 group in its molecule than the next preceding member. In the example of xylene, the homologous series is: Benzene C_8H_5, Toluene C_7H_8, and Xylene C_8H_{10}.

Attachment C13-2: Sample SPCC Plan Table of Contents

Purpose: To provide an example of a table of contents for an SPCC Plan that addresses the governing regulatory requirements.

Instructions: Use this table of contents for an SPCC Plan as a framework for developing your own plan.

Attachment C13-2: Sample SPCC Plan Table of Contents

Attachment C13-2: Sample SPCC Plan Table of Contents

List of Tables

List of Attachments

1.0 Introduction

EPA laboratories generate a variety of wastes that must be properly managed. This section defines the processes that should EPA laboratories should develop and undertaken by EPA laboratories to manage their wastes and it helps laboratories create systems that will allow them to maintain compliance with federal regulations. State-specific waste management regulations may also apply to the laboratories and should be reviewed to determine requirements. Although state requirements are not specifically addressed in this manual, the waste management systems described within should allow laboratories to easily integrate the management of state waste requirements into their overall waste management program.

EPA Program Requirements

To properly handle an EPA laboratory's solid waste, the facility must:

- Establish a recycling program.
- Provide appropriate collection, storage, and disposal of non-hazardous waste.
- Arrange for proper collection, storage, transport, and disposal of infectious waste.
- Ensure proper collection, storage, transport, and treatment/disposal of hazardous waste.
- Train employees on responsibilities related to hazardous waste management.
- Develop and maintain required records and reports for hazardous waste.
- Ensure suitable waste management techniques are applied to radioactive waste.

Program Administration

To effectively implement a waste management program, responsibilities should be assigned for:

- Characterization of waste
- Verification of appropriate waste storage
- Arranging for waste collection, transport, and treatment/disposal
- Development and maintenance of required records and reports
- Development and presentation of employee training information

2.0 Waste Management Process Overview

All wastes generated by EPA laboratories should be managed using the same basic process. This process can be divided into the following steps:

Step 1	Identify and inventory all laboratory waste streams.
Step 2	Characterize the composition of each waste stream.
Step 3	Determine what regulations govern the management of each waste stream.
Step 4	Determine applicable collection and storage requirements.
Step 5	Determine applicable transportation and disposal requirements

Detailed information on each of these steps is provided in section 3.0 of this chapter.

Once the basic waste management process has been determined, identify and organize the systems necessary to fulfill waste management requirements. The EPA has developed policies that should be considered when planning waste management strategies. These policies specify the following strategies, in order of preference, for managing wastes:

Source elimination—remove waste at its origin by substituting less hazardous alternatives, managing inventory to include only necessary quantities, etc.

Source reduction—decrease consumption of a waste source by using only the smallest amount needed to effectively perform necessary activities; buy bulk source products to eliminate unnecessary packaging; segregate hazardous wastes from nonhazardous wastes; etc.

Recycling and reuse—use source byproducts more than once, reclaim wastes into reusable materials, etc.

Treatment—process wastes to eliminate or reduce hazardous components.

Land disposal—if wastes cannot otherwise be eliminated or reduced, dispose of them at approved landfills.

2.1 Roles and Responsibilities

All laboratory personnel should be responsible for managing wastes according to the aforementioned waste management strategies. Personnel responsible for establishing laboratory waste management policies, overseeing waste policy implementation, and implementing the waste management process identified in section 2.0 should be identified and formally notified of their responsibilities.

Responsibility for developing and maintaining required and supplementary waste management documentation (e.g., waste stream inventories, waste constituents, applicable federal and state regulations, personnel training certifications, waste accumulation start dates, waste manifests, etc.) should be formally designated to laboratory personnel.

2.2 Wastes Specific to EPA Laboratories

The following six general categories of waste may be found at EPA laboratories:

Nonhazardous waste—waste that resembles common household waste in content (e.g., paper, plastic, cans, etc.)

Hazardous waste—waste that is listed by the EPA as hazardous or that exhibits defined characteristics of flammability, reactivity, corrosivity, or toxicity

Infectious waste—waste that is derived from work procedures with biological agents at the occupational medicine clinic or first-aid treatment center

Radioactive waste—waste that has the potential for emitting alpha, beta, gamma, or neutron radiation.

Special waste—waste such as contaminated soils, waste oil, batteries, etc.

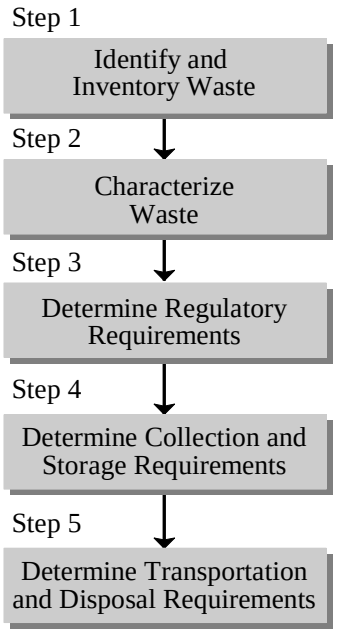
Polychlorinated biphenyl (PCB) waste—waste containing PCBs in quantities above established threshold levels

Specific waste management options for each of these waste types are described in sections 4.0 through 9.0.

3.0 Waste Management Process

To ensure that EPA laboratory waste streams are appropriately managed, the five basic steps of the waste management process should be followed at each laboratory. When appropriately evaluated and applied in their entirety, these steps constitute a comprehensive waste management process as summarized in Figure C14-1.

Figure C14-1: Waste Management Process



3.1 Step 1: Waste Identification and Inventory

To identify and inventory laboratory waste, consider the following questions:

- What are the waste streams generated at this laboratory?
- How much of each type of waste is generated?

A list of all specific types of wastes generated from laboratory activities should be created for each laboratory. This identification of waste streams should include all liquid, semisolid, and solid wastes from sources such as, but not limited to, the following:

- Laboratory activity/project wastes (e.g., experiment waste products, sample containers, etc.)

- Discarded and unused chemicals (e.g., outdated chemicals)

- Wastes associated with cleanup activities (e.g., materials used to clean up spilled chemicals, contaminated materials, etc.)

- Operational/maintenance activity wastes (e.g., used filters removed from laboratory hoods, etc.)

- Wastes associated with material receiving areas (e.g., packaging materials, damaged containers, etc.)

After all waste streams are identified, an inventory of the approximate amount of each waste stream generated per month should be calculated. The process used to arrive at these calculations (e.g., estimation, data from chemical purchase orders, process knowledge, etc.) should be documented.

Waste stream identification and associated inventories should be periodically (e.g., annually) reviewed and updated, as appropriate.

3.2 Step 2: Waste Characterization

To characterize laboratory wastes, consider questions such as:

- Which waste streams are considered "solid wastes?"
- Which waste streams are considered "hazardous?"
- Are any laboratory waste streams exempt from regulations?
- Do any laboratory solid wastes have specific management requirements?

All waste streams must be characterized as "hazardous" or "nonhazardous." In determining waste characterization, EPA laboratories should follow these guidelines that are highlighted in Figure C14-2.

3.2.1 Identify Solid Wastes

Identify those waste streams that are considered "solid wastes." According to federal regulations in 40 CFR 260, Appendix I, all materials can be classified as:

1) Garbage, refuse, or sludge; all solid waste.

2) Solid, liquid, semisolid, or contained gaseous material; all solid waste unless they are one of the five exclusions (e.g., spent sulfuric acid used to produce virgin sulfuric acid).

3) Something else other than solid waste.

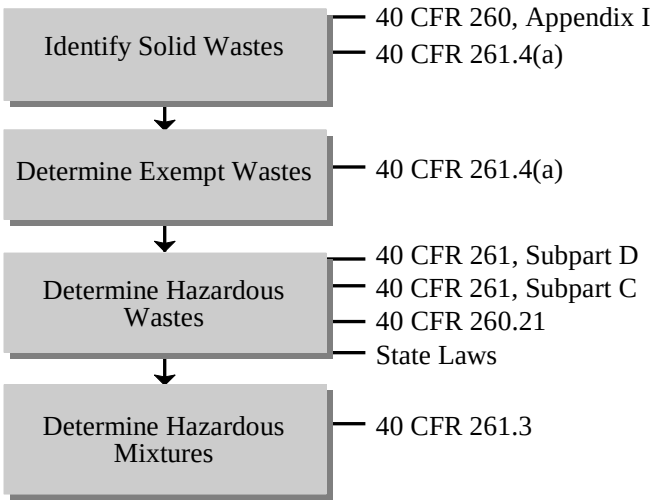
3.2.2 Determine Exempt Wastes

Determine if any laboratory solid wastes are exempt from hazardous waste regulation. Refer to 40 CFR 261.4(a) for a list of such wastes.

3.2.3 Determine Hazardous Wastes

Determine which solid wastes are considered "hazardous." A solid waste is considered hazardous if it is listed in Subpart D of 40 CFR 261 or if it meets certain criteria, identified in Subpart C of 40 CFR 261, for one of four hazardous waste characteristics (ignitability, corrosivity,

Figure C14-2: Waste Characterization Guidelines



reactivity, or toxicity). This determination can be based on analytical data (see Subpart C of 40 CFR Part 261 and 40 CFR 260.21) or on knowledge of both the process and the chemical and physical properties of the waste generated from the process.

Staff who understand a process can help to determine the chemical composition of waste generated by that process. Such wastes should be retested annually. All other wastes should undergo testing to determine if they are hazardous. Acceptable test methods are described in "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods," EPA Publication SW-846.

Solid wastes can also be considered hazardous under state law. For example, PCB wastes are considered hazardous in certain concentrations in California, Maryland, and Washington. Laboratory solid waste streams should be reviewed against any applicable state laws to determine whether they are considered hazardous. Figure C14-3 outlines the process of determining if solid wastes are hazardous.

3.2.4 Determine Hazardous Mixtures

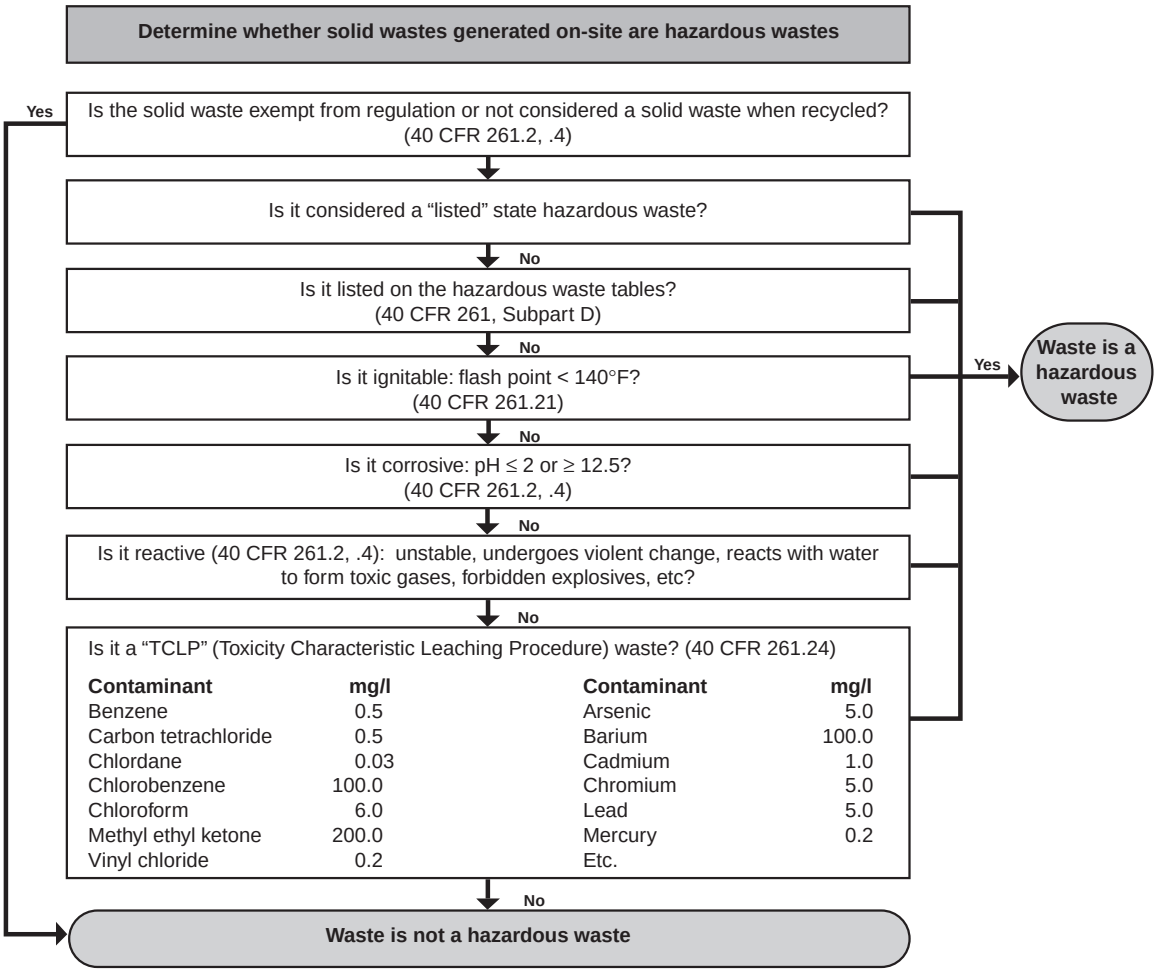
Determine whether any solid waste streams are subject to the federal "mixture and derived from" rules in 40 CFR 261.3. Listed hazardous wastes mixed with non-hazardous wastes, and residues resulting from the processing or managing of a listed hazardous waste, are considered hazardous.

3.3 Step 3: Applicable Regulations

To determine applicable regulations, consider the following questions:

- If hazardous wastes are generated at this laboratory, which generator regulations apply?
- Which regulations are applicable to other laboratory waste?

Figure C14-3: Waste Determination Summary



3.3.1 Hazardous Laboratory Wastes

The degree to which a laboratory is regulated by Subpart C of the Resource Conservation and Recovery Act (RCRA) depends upon the amount of hazardous waste generated and whether the laboratory transports, treats, stores, or disposes of such waste. After identifying and characterizing waste streams, each EPA laboratory should add together all of its approximate monthly individual hazardous waste stream amounts calculated in Step 1 to determine its generator status.

The maximum amount on-site at any one time should also be determined. Hazardous wastes that must be included in the generator calculation are specified in 40 CFR 261.5(c).

Conversions

lb/m	*x 0.4536*	=	*kg*
kg	*x 2.2046*	=	*lb/m*
gal (U.S.)	*x 3.785*	=	m^3
1 lb/m	*x 16.02*	=	*kg/m*

Generator status is divided into three types as shown in Table C14-1.

Table C14-1: Types of Hazardous Waste Generators

Generator Class	Calendar Month	At Any One Time
Conditionally Exempt Small Quantity Generator (CESQG)	≤ 100 kg hazardous waste ≤ 1 kg acutely hazardous waste < 100 kg contaminated waste from acutely hazardous waste spill	< 1,000 kg hazardous waste indefinitely
Small Quantity Generator (SQG)	100 - 1,000 kg hazardous waste ≤ 1 kg acutely hazardous waste	< 6,000 kg hazardous waste for up to 180 days
Large Quantity Generator (LQG)	> 1,000 kg hazardous waste > 1 kg acutely hazardous waste	> 6,000 kg hazardous waste for up to 90 days

A different but similar set of regulations applies to each type of generator. Management of hazardous wastes is further described in Section 5.0.

3.3.2 Other Laboratory Wastes

Applicable federal and state regulations for other types of EPA laboratory wastes (i.e., nonhazardous, infectious, radioactive, special, and PCB wastes) should be followed. At a minimum, EPA laboratories should develop and implement waste minimization and pollution prevention activities that eliminate or reduce both the amount of laboratory waste and the environmental impacts associated with of such wastes. These techniques are discussed further in Chapter C9 of this manual.

Management of these types of wastes is further described in Sections 4.0, and 6.0 through 9.0

3.4 Step 4: Collection and Storage Requirements

To plan for appropriate waste collection and storage, consider the following questions:

- How should laboratory wastes be stored?
- What types of waste collection programs/activities should be available at EPA laboratories?
- What are some guidelines for proper waste container management?

EPA program requirements mandate that EPA laboratories do the following with regards to waste collection and storage.

In general, the collection and storage of laboratory wastes should be consistent with the following practices:

- Segregate waste streams (to avoid incompatibility incidents).

- Label each container with the name of the waste it contains.

> *Note: Waste containers that are too small to be labeled can be collected and packed (by type of waste) into a larger, compatible, labeled container.*

- Avoid mixing hazardous and non-hazardous wastes.
- Ensure that incompatible materials stored close to each other are separated by a dike, berm, wall, or other device.
- Ensure that wastes are stored so as to minimize spills, leaks, or ruptures.
- Manage all unidentifiable wastes as hazardous (until positive identification is made).
- Close containers during storage.
- Avoid storing/stacking waste containers in high traffic areas.
- Ensure that storage areas are adequately vented.
- Avoid placing waste in an unwashed container that previously held an incompatible material.

In addition, waste accumulation and storage areas should be inspected periodically (e.g., weekly). Such inspections should be documented, with any identified deficiencies promptly corrected. Attachment C14-1 includes an inspection checklist.

Specific collection and storage guidelines for EPA laboratory waste streams are provided in Sections 4.0 through 9.0.

3.5 Step 5: Transportation and Disposal Requirements

Consider the following questions related to transportation and disposal of wastes:

- How should laboratory wastes be transported off-site?
- What types of disposal options are available for the identified waste streams?
- What is the laboratory's responsibility after the waste leaves the laboratory?

Laboratories are ultimately responsible for the wastes they produce. All laboratory wastes that are removed from the lab for off-site treatment and/or disposal should therefore be transported, treated, and/or disposed of in an environmentally sound manner. While EPA laboratories do not typically transport wastes, it is important that all contractors hired to perform such services are appropriately trained for such tasks and use appropriate transportation vehicles, equipment, and procedures (e.g., vehicles should be cleaned at least weekly, solid waste should be removed from vehicles within 24 hours, etc.). In addition, knowledgeable laboratory personnel should be responsible for overseeing such services.

EPA's waste management strategies identified in section 2.0 promote (where feasible) the use of source elimination, source reduction, and recycling/reuse over waste treatment and land disposal. The current regulatory trend is to reduce the amount of waste added to landfills by requiring waste

generators to examine implementing source elimination/reduction, recycling/reuse, and treatment options before considering land disposal.

In determining which waste management strategy(ies) to employ, EPA laboratories should consider issues summarized in Figure C14-4.

- Potential environmental consequences if wastes are improperly managed
- Cost of implementing management strategy(ies)
- Short-term costs versus long-term gains
- Future business opportunities/ objectives
- Community relations
- New/pending environmental regulations

Additional transportation and disposal considerations specific to EPA laboratory waste streams are discussed in sections 4.0 through 9.0.

3.6 Other Considerations

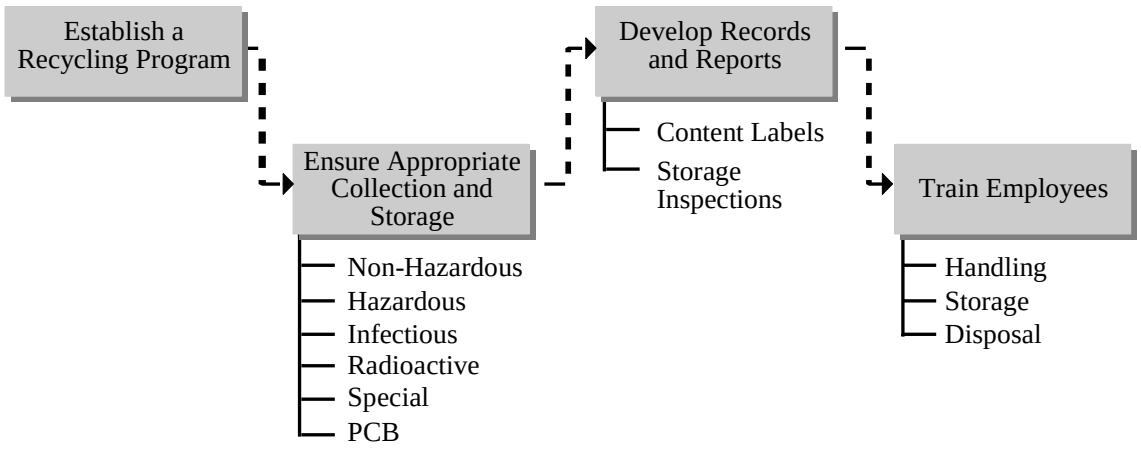
Two additional topics—waste minimization and documentation—should also be considered when developing, implementing, and maintaining a waste management system.

3.6.1 Waste Minimization

Because of the growing emphasis placed on source elimination, source reduction, and recycling/reuse waste management strategies, waste minimization plays an increasingly important role in a laboratory's waste management process. Laboratories should strive to develop waste minimization programs that reduce the amount of wastes generated and/or limit the types of wastes generated to those that are less hazardous or nonhazardous.

The checklist in Attachment C14-2 provides a listing of techniques that should be considered in the waste minimization process.

Figure C14-4: Waste Management Considerations



3.6.2 Documentation Aspects

Various types of documentation are generated during, and in support of, the waste management process. All EPA laboratories should establish formal systems to organize and control waste documentation. Any existing regulatory record retention time frames should be followed.

Waste management documentation includes, but is not limited to, the following:

- Waste identification and inventory records
- Hazardous waste shipment manifests
- Accumulation and storage area inspection forms
- Training records for employees/ contractors who handle, treat, transport, and/or dispose of wastes
- Agreements regarding contracted waste management services
- Chain-of-custody forms for laboratory samples/off-site waste shipments
- Content labels on waste containers

4.0 Nonhazardous Waste

Nonhazardous wastes are those wastes that are not defined as hazardous under federal or state law. It is important to note that, while such wastes are not regulated as hazardous, other regulations governing their management may apply. For example, all nonhazardous wastes may be subject to waste minimization and pollution prevention initiatives.

4.1 Identification and Inventory

Types of nonhazardous waste streams that may be present at EPA laboratories include the following:

- Food refuse
- Paper-related trash (e.g., packaging materials, used photocopy paper, etc.)
- Plastic garbage (e.g., used utensils, packaging materials, etc.)
- Chemical wastes determined to be nonhazardous

The amounts of such wastes should be periodically calculated (e.g., monthly), with results tracked to determine approximate annual usage. Such data can then be compared to previous and future data to determine nonhazardous waste minimization trends and opportunities.

4.2 Characterization

Laboratories should determine whether new/atypical chemical wastes are nonhazardous through analytical tests or process knowledge. Wastes characterized as nonhazardous should be reviewed annually to ensure that they still meet non-hazardous criteria.

4.3 Applicable Regulations

The collection and disposal of nonhazardous waste is regulated by Subtitle D of RCRA. Most states have promulgated additional regulations governing the construction and operation of nonhazardous waste disposal facilities, mostly incinerators and landfills. The regulation governing nonhazardous waste directly applicable to EPA laboratories is 40 CFR 243.

4.4 Collection and Storage

Nonhazardous waste must be stored in a manner that neither constitutes a fire, safety, or health hazard, nor provides

food or shelter for pests. All solid waste containing food wastes must be securely stored in covered or closed containers that are nonabsorbent, leakproof, durable, easily cleanable (if reuseable), and designed for safe handling. Containers must be maintained in a clean condition.

Reusable waste containers that are emptied manually must not exceed 75 pounds (34.05 kg) when filled, and must be capable of being serviced without the collector coming into physical contact with the solid waste.

In the design of all buildings or other facilities that are constructed, modified, or leased after the effective date of regulatory guidelines, there must be provisions for storage that will accommodate the volume of solid waste anticipated. Storage areas must be easily cleaned and maintained, and must allow for efficient and safe collection.

4.5 Transportation and Disposal

If nonhazardous wastes cannot be eliminated, reduced, recycled, and/or treated, the laboratory should properly transport and dispose of such wastes. While EPA laboratories do not operate transportation and disposal facilities, EPA laboratories are responsible for ensuring that the contracted transportation and disposal facility has all appropriate permits and approvals.

5.0 Hazardous Waste

Hazardous wastes must be managed from "cradle to grave"; that is, specific federal and, in many cases, state and local laws require that hazardous wastes be:

- Identified and characterized upon generation
- Stored in appropriate containment areas for finite time periods
- Sent to licensed facilities for ultimate treatment, storage, and/or disposal

5.1 Identification and Inventory

Types of hazardous waste streams that may be present at EPA laboratories include, but are not limited to, the following:

- Spent solvents (e.g., methylene chloride, tetrachloroethylene, acetone, etc.)
- Petroleum sludges
- Various organic chemical residues (e.g., distillation bottoms from the production of acetaldehyde from ethylene, etc.)
- Certain "off-specification" chemicals (e.g., acetic acid, benzene, etc.)

EPA laboratories must maintain an accurate inventory of hazardous wastes contained in satellite accumulation areas and temporary (post satellite) accumulation areas to determine generator status and to facilitate accurate reporting.

5.2 Characterization

Federal regulations require generators to determine if generated wastes are hazardous. If a laboratory generates solid wastes, it must determine if such wastes are hazardous using the following method (as identified in 40 CFR 262.11):

- Determine if the waste is excluded from regulation under 40 CFR 261.4.

- Determine whether the waste is listed as a hazardous waste in Subpart D of 40 CFR 261.

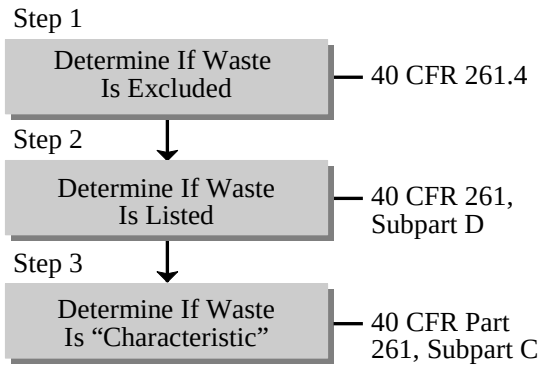
- If it is not listed as a hazardous waste in Subpart D of 40 CFR 261, determine whether the waste is identified in Subpart C of 40 CFR 261 as exhibiting ignitability, corrosivity, reactivity, or toxicity characteristics.

RCRA regulations in 40 CFR Part 261 list over 100 industrial waste streams as hazardous (the F- and K-listed wastes). These wastes are listed because they either exhibit one or more of the characteristics of hazardous waste or contain specific toxic components at levels deemed hazardous.

The EPA has also designated approximately 200 discarded commercial chemical products as acute hazardous wastes (the P-list wastes), and approximately 450 other chemical products as hazardous wastes (the U-list wastes). To qualify as a listed waste under the P or U list, the chemical product must be disposed of as a commercially pure grade of the chemical (any technical grade of the chemical and all formulations in which the chemical is the sole active ingredient). However, if the chemical enters a mixture or a reaction that is part of a manufacturing process, the manufacturing process waste is not considered a listed waste unless either the manufacturing process itself is listed (F- or K-listed wastes) or the waste exhibits hazardous characteristics as defined in 040 CFR Part 261, Subpart C (i.e., corrosivity, ignitability, reactivity, or toxicity characteristics).

Characteristic metal wastes are generated by academic institutions, industry, nuclear utilities, and government and medical facilities. This waste category is dominated by lead and lead shielding, mercury, cadmium, and chromium. Typical characteristic organic wastes include chloroform, methanol, and pesticides. Some waste streams exhibiting the characteristics of both ignitability and toxicity are also identified as characteristic organic waste. The hazardous waste characterization process is summarized in Figure 14-5.

Figure C14-5: Hazardous Waste Characterization



5.3 Applicable Regulations

Subpart D of 40 CFR 261 specifies the wastes that must be included in the hazardous waste generator quantity determination. Wastes that are excluded from regulation are identified in Subpart C of 40 CFR 261 and include the following:

- Waste exempt from regulation under:
  - 40 CFR 261.4(c) through (f) in-process material, samples, and treatability studies
  - 40 CFR 261.6(a)(3) (reclaimed industrial ethyl alcohol)
  - 40 CFR 261.7(a)(1) (waste left in an empty container or liner)
  - 40 CFR 261.8 (PCB wastes regulated under the Toxic Substances Control Act)

- Waste managed immediately upon generation only in on-site elementary neutralization units, wastewater treatment units, or totally enclosed treatment facilities as defined in 40 CFR 260.10

- Waste that is recycled, without prior storage or accumulation, only in an on-site process subject to regulation under 40 CFR 261.6(c)(2)

- Used oil managed under the requirements of 40 CFR 261.6(a)(4) and 40 CFR 279

- Spent lead-acid batteries managed under the requirements of 40 CFR 266, Subpart G

- Universal waste (currently batteries, pesticides and thermostats) managed under 40 CFR 261.9 and 40 CFR 273

States may have their own hazardous waste regulations, which will be at least as stringent as federal regulations. Laboratories should determine whether state regulations exist and whether such regulations are applicable to laboratory operations. A hazardous waste management program that addresses both the federal and the state requirements should then be developed and implemented.

5.4 Collection and Storage

Federal regulations identifying collection and storage requirements applicable to generators of hazardous waste are listed in 40 CFR 262. The extent of regulation depends on a laboratory's generator classification (i.e., conditionally exempt small quantity, small quantity, or large quantity). Table C14-1 summarizes these classifications.

5.4.1 Registering as a Hazardous Waste Generator

If a laboratory generates hazardous wastes in any amount, it must register with the EPA (49 CFR 262.12). The registration form ("Form 8700-12") includes a listing of all wastes generated and a listing of all hazardous waste activities (i.e., generator, transporter, treatment, storage, and/or disposal) conducted at the laboratory.

Upon review of the form, the EPA will issue the laboratory an EPA identification number. This number should be referenced in any contact with the EPA concerning hazardous waste issues.

5.4.2 Hazardous Waste Accumulation Provisions

Federal regulations delineate two types of hazardous waste storage areas: satellite accumulation and 90-day for large quantity generators (LQGs), 180-day accumulation areas for small quantity generators (SQGs).

Satellite Accumulation

Hazardous wastes or wastes of unknown compositions or regulatory applicability may be accumulated at the point of generation subject to requirements for satellite accumulation. The key constraint on these storage areas is the volume of waste that can be stored in the area. The satellite accumulation regulations allow generators to accumulate as much as 55 gallons of hazardous waste, or one quart of acutely hazardous waste listed in 40 CFR 261.33(e), in containers at or near any point of generation which is under the control of the operator of the process, provided the container:

- Is maintained in good condition (e,g., does not leak, is not rusting, etc.)
- Is compatible with the waste it contains
- Is kept closed during storage, except when it is necessary to add or remove waste
- Is labeled either with the words "Hazardous Waste" or with other words that identify the contents of the container

When more than 55 gallons of hazardous waste or 1 quart of acutely hazardous waste are accumulated, the generator must remove the "excess" waste within 3 days either to a temporary accumulation area, or directly to a licensed treatment, storage, and disposal facility (TSDF). The generator must mark the container holding the excess accumulation of hazardous waste with the date the excess amount began accumulating.

The phrase "at or near any point of generation where wastes initially accumulate, which is under the control of the operator of the process generating the waste" has been subject to a wide variety of interpretation by state and federal regulatory agencies. In general, a waste container located next to laboratory equipment or a process generating the waste is "at or near the point of generation." A container for waste solvents located in a room that collects waste from several different laboratories will not likely be considered "under the control of the operator of the process generating the waste." The main concern of regulators is mixing the incompatible waste. Some laboratories install locks on containers; other require personnel adding waste to a container to include information regarding added wastes in a log.

90- or 180-Day Accumulation

LQGs and SQGs that lack permitted or interim-status TSDFs must accumulate containers of hazardous waste that are no longer eligible for satellite accumulation, in a 90- or 180-day accumulation area. The key constraint on these storage areas is the amount of time that waste can be stored. LQGs are allowed 90 days of accumulation and SQGs are allowed 180 days. For unknown wastes undergoing sampling and analysis, the start date of accumulation is when the waste is generated, not when it is determined by analysis to be hazardous. Therefore, it is important to manage an unknown waste as hazardous until it is proven otherwise.

Waste accumulation areas have specific design and operational requirements that depend on whether the generator is a SQG or LQG. Once waste is removed from a

satellite area, it may be managed in containers, tanks, drip pads, or waste piles. Note that there are occasions when more than 55 gallons of waste is generated by a process when waste will not be managed in a satellite accumulation area. Rather, this waste will be directly placed in 90- or 180-day accumulation.

Accumulation Practices Applicable to Both 90- and 180-Day Accumulation Areas

The following waste accumulation practices should be established and followed at 90- and 180-day accumulation areas:

- The date accumulation begins must be clearly marked and visible for inspection on each container.

- While being accumulated on-site, each container and tank must be labeled "Hazardous Waste" or with an EPA hazardous waste label.

- The generator must comply with 40 CFR 265, Subpart C (Preparedness and Prevention), which requires maintenance and operations of the facility to minimize the potential for a release to the environment. All facilities must be equipped with the following, unless none of the hazards posed by waste handled at the facility could require a particular kind of equipment specified below:

  — An internal communications or alarm system capable of providing immediate emergency instruction (voice or signal) to facility personnel

  — A device, such as a telephone (immediately available at the scene of operations) or a hand-held two-way radio, capable of summoning emergency assistance from local police departments, fire departments, or state or local emergency response teams

  — Portable fire extinguishers, fire control equipment (including special extinguishing equipment, such as that using foam, inert gas, or dry chemicals), spill control equipment, and decontamination equipment

  — Water at adequate volume and pressure to supply water hose streams, or foam-producing equipment, or automatic sprinklers, or water spray systems

- Emergency equipment must be tested and maintained as required to ensure that it will work if needed in an emergency.

- Aisle space must be sufficient to allow unobstructed movement of personnel, fire protection equipment, spill control equipment, and decontamination equipment to any area of facility operation in an emergency, unless aisle space is not needed for any of these purposes.

The checklist provided in Attachment C14-3 can be used as a guide for inspecting hazardous waste accumulation areas.

5.4.3 Large Quantity Generators (LQGs)

In addition to the waste accumulation requirements applicable to both 90- and 180-day accumulation areas, LQGs must comply with the following requirements:

Method of Accumulation

If waste is accumulated in containers, they must conform to 40 CFR 265, Subpart I, which requires that containers be in good condition and compatible with the waste. Containers must be kept closed except when adding or removing waste and they must be managed to minimize the potential for a leak. Weekly inspections of containers must be performed to detect any signs of leaks or container failure. Incompatible wastes must be separated by physical means, and flammable waste must be accumulated greater than 50 feet from the property boundary. There are also air emission standards defined in 40 CFR 265, Subparts AA, BB, and CC that may apply.

If waste is accumulated in tanks, then the provisions of 40 CFR 265, Subpart J apply, except 40 CFR 265.197 and 265. 200. Sub-part J imposes a variety of requirements including, but not limited to, integrity testing, secondary containment, fill/overfill protection, daily inspections, and air emission standards defined in 40 CFR 265, Subpart AA, BB, and CC.

EPA laboratories do not accumulate waste on drip pads, nor accumulate waste in containment buildings, therefore they are not addressed in this manual.

Contingency Plan

The laboratory must prepare a contingency plan that documents the laboratory preparedness and prevention measures required by 40 CFR 265, Subpart C, designed to minimize hazards to human health or the environment from fires, explosions, or any unplanned sudden or non-sudden release of hazardous waste or hazardous waste constituents to air, soil, or surface water. The plan must include the following elements (as identified in 40 CFR 265, Subpart D):

- A description of the actions laboratory personnel must take in response to fires, explosions, or any unplanned sudden or non-sudden release of hazardous waste or hazardous waste constituents to air, soil, or surface water at the facility (Contingency plan requirements can be integrated with another emergency plan such as a Spill Prevention, Control, and Countermeasures (SPCC) Plan. Refer to Chapter 13 of this manual for SPCC plan requirements.)

- A description of the arrangements agreed to by local police departments, fire departments, hospitals, contractors, and state and local emergency response teams to coordinate emergency services

- A list of names, addresses, and phone numbers (office and home) of all persons qualified to act as emergency coordinator (this list must be kept up-to-date. Where more than one person is listed, one must be named as primary emergency coordinator and

thers must be listed in the order in which they will assume responsibility as alternates)

- A list of all emergency equipment (such as fire extinguishing systems, spill control equipment, communications and alarm systems [internal and external], and decontamination equipment), and its location at the laboratory, a physical description of each item, and a brief outline of its capabilities

- An evacuation plan for laboratory personnel where there is a possibility that evacuation could be necessary. (This plan must describe signal(s) to be used to begin evacuation, evacuation routes, and alternate evacuation routes (in cases where the primary routes could be blocked by releases of hazardous waste or fires.)

Copies and subsequent revisions of the contingency plan should be maintained at the laboratory and submitted to local police departments, fire departments, hospitals, and state and local emergency response teams. Refer to Chapter G of this manual for information on emergency planning.

Land Disposal Restrictions

If the laboratory is treating waste subject to the land disposal restrictions (40 CFR 268) in tanks or containers, it must develop and follow a written waste analysis plan that describes the procedures to ensure compliance with the treatment standards. The plan must be kept at the laboratory and must include a detailed chemical and physical analysis of a representative sample of the prohibited waste(s) being treated that includes all information necessary to treat the waste(s) in accordance with the regulations, including the selected testing frequency. The plan must be filed with the EPA Regional Administrator (or a state authorized to implement the land disposal restriction requirements) a minimum of 30 days prior to the treatment activity, with delivery verified.

An extension may be granted by the applicable regulatory agency if hazardous wastes must remain on-site for longer than 90 days due to unforeseen, temporary, and uncontrollable circumstances. The extension of up to 30 days may be granted at the discretion of the Regional Administrator on a case-by-case basis.

5.4.4 Small Quantity Generators (SQGs)

An SQG may accumulate hazardous waste on-site for 180 days or less (270 days or less if the waste must be transported over a distance of 200 miles or more for off-site treatment, storage or disposal). An extension of up to 30 days may be granted at the discretion of the applicable regulatory agency.

SQGs that accumulate waste in containers must adhere to the standards set forth in 40 CFR 265, Subpart I except for the air emission standards and the requirement to locate ignitable or reactive waste greater than 50 feet from the property line. For waste accumulated in tanks, the SQG must comply with the requirements specified in 40 CFR 265.201 (e.g., daily inspections).

n addition to the requirements applicable to both 90- and 180-day accumulation areas, SQGs must comply with the following:

- There must be at least one employee (the emergency coordinator) either on the premises or on call (i.e., available to respond to an emergency and arrive at the laboratory within a short period of time) with the responsibility for coordinating all emergency response measures.

- The following information must be posted next to the telephone:
  - The name and telephone number of the emergency coordinator
  - Location of fire extinguishers and spill control material, and (if present) the fire alarm
  - The telephone number of the fire department, unless the laboratory has a direct alarm

- All employees must be familiar with responding to emergencies and proper waste handling procedures in their work area.

- The emergency coordinator or his/her designee must respond to any emergencies that arise.

5.4.5 Personnel Training

LQGs and TSDFs are required to develop and implement a training program, as required by 40 CFR 262.34 and 265.16. SQGs must ensure that their personnel are familiar with hazardous waste management; a training program for SQGs is a good management practice. Refer to Chapter C3 of this manual for more information on training.

5.5 Transportation and Disposal

Most hazardous waste at EPA laboratories will require shipment to an off-site TSDF. The EPA requires that all hazardous wastes be managed from "cradle to grave." The hazardous waste regulations place the burden of compliant shipping on the generator. Most generators contract for waste transportation with a professional trucking company, which assists with ensuring proper packaging and labeling requirements prior to shipment.

5.5.1 Pre-Transport Requirements

The first step in cradle-to-grave tracking of hazardous wastes is at the pre-transport stage. In order to ship containers of hazardous wastes off-site, generators must comply with the following pre-transport requirements, as identified in 40 CFR 262.30 to .33:

- Affix an EPA hazardous waste label to the container package

- Complete the EPA label with the required information as specified in 40 CFR 262.32 and 49 CFR 172 (e.g., EPA waste ID number, hazard class, accumulation start date, etc.)

- Identify any land-ban-restricted wastes

- Prepare manifests

- Make placards available to transporters

5.5.2 Placarding

Placards that indicate the hazards of the cargo must be placed on the end and sides of the transport vehicle. Tables 1 and 2 in 49 CFR 172.504 identify classes of hazardous materials and placarding requirements consistent with 40 CFR 262.30 and .31.

5.5.3 Manifest System

The manifest is used to convey hazardous waste from the generator to the transporter and then to the TSDF. The form of the manifest can vary by state. Generators must complete the manifest form of the state to which the waste will be transported. If the receiving state does not have a manifest, then the manifest for the state in which the waste is generated should be completed. If neither the receiving nor the sending state has a manifest, then the federal form may be completed.

The manifest is a multiple-copy form. The generator and the transporter sign and date the completed manifest and the transporter retains the form. A representative from the designated TSDF signs the manifest when the waste is delivered and returns a signed copy to the generator. If the generator does not receive a copy of the manifest from the TSDF, certain actions are required, depending on the generator status.

An LQG must contact the TSDF if the manifest is not received within 35 days of the date of initial shipment. If the LQG has not received the manifest copy within 45 days, then the LQG must file an exception report with the regulatory agency. The exception report should include:

- A legible copy of the manifest for which the generator does not have confirmation of delivery
- A cover letter signed by the generator or his/her authorized representative explaining the efforts taken to locate the hazardous waste and the results of those efforts

An SQG who does not receive a copy of the manifest with the handwritten signature of the owner or operator of the designated facility within 60 days of the date the waste was accepted by the initial transporter must submit a legible copy of the manifest, with some indication that the generator has not received confirmation of delivery.

[Note: Conditionally-exempt small quantity generators (CESQGs) are exempt from manifesting requirements as well as transport requirements in the hazardous waste regulations. However, U.S. Department of Transportation regulations for transporting hazardous materials may apply.]

In addition to the manifest, the generator must notify the TSDF of the status of the waste with respect to the land disposal restrictions (LDRs). If the waste does not meet the applicable treatment standard in 40 CFR 268, then the generator must notify the TSDF in writing. If the waste does meet the applicable treatment standard, then the generator must certify this fact. Most commercial TSDFs have a standard LDR form that contains the required information.

The hazardous waste regulations place the burden of ensuring that waste is properly packaged, labeled, and placarded on the generator; 40 CFR 262.30 to .33 contain specific requirements that are almost identical to the Department of Transportation (DOT) regulations.

5.5.4 Treatment

There are two major categories of treatment that are apply to EPA laboratories: generator treatment and treatment at a facility with a permit or interim status. Generator treatment may be performed on-site in tanks or containers (or containment buildings) in conformance with the genera-tor requirements in 40 CFR 262. Generator treatment commonly includes gravity separation, elementary neutralization, and chemical precipitation. The standards for generator treatment are the same as for 90- and 180-day hazardous waste accumulation operations. Refer to section 5.4 of this chapter for those requirements.

Note that the addition of absorbent material to waste in a container or the addition of waste to the absorbent material in a container is allowed, provided:

- These actions occur at the time waste is first placed in the containers.
- Such mixing does not result in incompatible waste reactions.
- The container does not leak.
- The container is compatible with the mixture.

EPA laboratories typically do not have permitted or interim status treatment facilities. Rather, they send waste to a licensed off-site facility. As a good management practice, EPA laboratories should perform necessary research on prospective treatment vendors to ensure that EPA laboratory waste is managed in accordance with required regulations.

5.5.5 Storage

On rare occasions some EPA laboratories may store waste for longer periods than allowed under the generator regulations (i.e., 90 days for LQGs and 180 days for SQGs, with few exceptions). Such storage is permitted only if the laboratory has been granted a hazardous waste permit or interim status. The standards for managing a permitted or interim status laboratory are extensive. In addition to all of the requirements discussed for LQGs, a storage facility must establish a comprehensive inspection program, design tank or container storage areas to minimize the potential for a release, and implement additional recordkeeping requirements. The interim status standards for container and tank storage are discussed in 40 CFR 265, Subparts I and J, respectively.

5.5.6 Disposal

EPA laboratories do not operate hazardous waste treatment storage and disposal facilities. Laboratories who contract with hazardous waste TSDFs should review regulatory status and history of vendors to ensure minimal risk to the EPA. In particular, the contracted TSDF should treat EPA waste such that they meet the land disposal restriction requirements prior to land disposal.

5.6 Recordkeeping and Reporting

Generators have a number of recordkeeping and reporting requirements that vary, depending on generator status.

5.6.1 LQGs

An LQG must maintain the following records:

- A copy of each manifest signed by the designated TSDF that received the waste (If the manifest is not received signed from the TSDF [in which case an exception report would need to be submitted], then the LQG must keep the copy of the manifest signed when the shipment was provided to the transporter. These records must be retained for at least three years from the latest date on the manifest.)
- A copy of each biennial report and exception report for a period of at least three years from the due date of the report
- Any test results, waste analyses, or other waste determinations for at least three years from the date that the waste was last sent to a TSDF
- Training records on current personnel (These must be kept until closure of the laboratory. Training records on former employees must be kept for at least three years from the date the employee last worked at the laboratory.)
- Copies of all notices, certifications, demonstrations, waste analysis data, and other documentation produced pursuant to the LDRs for at least five years from the date that the waste that is the subject of such documentation was last sent for on-site or off-site treatment, storage, or disposal

An LQG must prepare and submit a biennial report due March 1 of each even numbered year. The biennial report must be submitted on a form prescribed by the applicable regulatory agency and must include the following information:

- The EPA identification number, name, and address of the generator
- The calendar year covered by the report
- The EPA identification number, name, and address for each TSDF in the United States to which waste was shipped during the year
- The name and EPA identification number of each transporter used during the reporting year for shipments to a TSDF within the United States
- A description, EPA hazardous waste number, DOT hazard class, and quantity of each hazardous waste shipped off-site for shipments to a TSDF within the United States
- A description of the efforts undertaken during the year to reduce the volume and toxicity of waste generated
- A description of the changes in volume and toxicity of waste actually achieved during the year in comparison to previous years

5.6.2 SQGs

An SQG must maintain the following records:

- A copy of each manifest signed by the designated TSDF that received the waste. If the manifest is not received signed from the TSDF then the SQG must keep the copy of the manifest signed when the shipment was provided to the transporter. These records must be retained for at least three years from the latest date on the manifest.

- Any test results, waste analyses, or other waste determinations for at least three years from the date that the waste was last sent to a TSDF.

5.6.3 CESQGs

Although CESQGs do not have specific recordkeeping and reporting requirements in the regulations, it is a good management practice to maintain copies of waste determinations, shipping papers, and other documentation necessary to demonstrate that the laboratory generated and accumulated wastes in such quantities as to justify the designation of the laboratory as a CESQG.

6.0 Infectious Waste

EPA laboratories may generate infectious wastes through both occupational health and research activities. Information regarding infectious materials is included in Chapter C7 of this manual.

6.1 Identification and Inventory

Types of infectious waste streams that may be present at EPA laboratories include the following:

- Pathological specimens (e.g., tissues, blood samples, excreta, secretions from patients/laboratory animals, etc.)

- Any substance that may harbor or transmit pathogenic organisms

Although the amounts of such wastes may vary considerably, depending on the nature of current laboratory experiments, laboratories should attempt to quantify and track the approximate usage. Several states require generators to complete annual reports of the amount of infectious waste generated.

6.2 Characterization

Laboratories should ensure that infectious wastes are appropriately characterized and managed in accordance with applicable federal and state regulations.

6.3 Applicable Regulations

Federal regulation 40 CFR 243, "Guidelines for the Storage and Collection of Residential, Commercial, and Institutional Solid Waste," governs the collection of infectious waste. The section on radioactive waste discusses management of infectious waste with radioactivity. Typically, states have specific regulations for managing infectious waste.

6.4 Collection and Storage

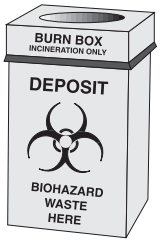
Infectious waste should be segregated from other wastes into containers that prevent contact with infectious agents. Infectious wastes must never be handled without protective gloves.

Generally, "sharps" (e.g., broken glassware, needles) should be contained in rigid plastic con-tainers displaying the universal biohazard symbol. Other infectious wastes may be stored in plastic bags displaying the universal biohazard symbol. Containers should be covered and secured from unauthorized access.

6.5 Transportation and Disposal

The majority of infectious waste generated by EPA laboratories will be transported off-site by a licensed medical waste vendor for ultimate treatment and disposal. The vendor will provide instructions on proper packaging of the waste. Generally, the container must be labeled with generator identification information and the biohazard label or equivalent.

Some states require that transporters of infectious waste maintain certain permits; each EPA laboratory should consult its state's regulations to determine if this requirement is applicable.



Some facilities may operate an autoclave or other device to pretreat waste prior to disposal. Autoclaving destroys biological agents and renders the resultant waste noninfectious. For facilities that treat infectious waste, it is important to develop a procedure describing the specific steps for operating the treatment system, including:

- Waste acceptance criteria
- Unit operation
- Unit maintenance program
- Recordkeeping

EPA laboratories that employ vendors for infectious waste treatment and/or disposal must verify that the vendor has all appropriate approvals to manage such waste. In addition, EPA laboratories should retain records of any infectious waste disposed.

[Note: Several states require generators to complete manifests.]

7.0 Radioactive Waste

Although a separate issue from the disposal of hazardous waste, the handling and disposal of radioactive wastes should be clearly addressed in all EPA laboratory waste management programs. Because of the unique hazards associated with radioactive materials, this aspect of the waste management program should be implemented and overseen by the Radiation Safety Officer (RSO) or other qualified person with experience in radiation safety.

This section of the manual outlines the low-level radioactive waste (LLRW) management guidelines and procedures in effect at EPA laboratories. For more information on radiation safety practices refer to Chapter C6 of this manual. The radioactive waste generated at EPA laboratories is primarily managed by decay-in-storage, sanitary sewer disposal, and interim storage pending final disposition (e.g., off-site burial, or incineration).

In the interest of occupational and public safety and health, as well as maintaining exposures as low as reasonably achievable (ALARA), the length of time LLRW is placed in storage should be kept to a minimum. Also, radioactive waste should be treated, either on or off-site, to the

maximum extent possible, to achieve maximum volume reduction prior to landburial.

7.1 Identification and Inventory

Radioactive waste results from the use of radioisotopes, which can be found in either liquid or solid form, or from radiation-generating machines. Waste is segregated according to physical form (e.g., liquid, solid, scintillation vials, etc.) and by radionuclide. Since the cost of disposal will depend directly on the volume and weight of the radioactive waste produced, minimization of radioactive wastes is essential, and requires advanced planning, facility and equipment design, and control of work methods. It is essential to separate ordinary nonradioactive trash from solid radioactive waste at the point of origin. For this reason, solid radioactive waste containers should be clearly identified with the radiation symbol and easily distinguishable from ordinary trash containers.

Radioactive waste streams generated should be continually evaluated to ensure that reasonable waste avoidance techniques are employed. The major radioactive waste streams produced at EPA laboratories include solids; liquids; liquid scintillation vials; and animal carcasses, parts, or bedding. Each of these categories are in Table C14-2.

7.2 Radioactive Waste Characterization

All waste streams must be characterized to determine an appropriate means of disposal. Before a new project or process can be initiated, the project officer or branch chief managing the project must present a plan for waste disposal to the RSO and SHEMP Manager. This plan must include:

- A waste volume estimate
- Chemical form(s)
- The anticipated activity of the waste (specific and total)
- The number and frequency of waste samples to be analyzed

When historic data are available for a particular group of samples and the waste streams have been previously analyzed, it may be possible to analyze the waste streams using a representative percentage of samples to verify previously observed trends. When these data are not available, a representative sample from all waste streams must be collected for analysis. Sample screening data, obtained after sample receipt, can be used to select an appropriate sample for waste stream analysis. Samples suspected of containing the highest concentrations of radioactive materials should be selected for waste stream characterization.

All waste analysis results submitted to the RSO must be in writing. After evaluation by the RSO, a copy of the results must be returned to the employee with recommendations for disposal. If the waste requires off-site disposal, the RSO must make the appropriate arrangements.

7.3 Applicable Regulations

The Nuclear Regulatory Commission has regulatory authority over storage and disposal of all LLRW. Regulations require conformance with minimum acceptable

Table C14-2: Radioactive Waste Streams

Type	Example
Solid	Paper, plastic, gloves, bench covers, Eppendorf tubes
	Liquid scintillation vials
	Environmental samples (e.g., soil, rock)
	Precipitates, resins, residues
Liquid	Acids, solvents, washwater
	Environmental samples
Animals	Carcasses, tissues, organs, excreta, bedding

performance criteria for waste management activities, while providing for flexibility in technological approach. These criteria and guidelines are designed to ensure adequate protection of the public safety and health, and the environment.

LLRW are commonly buried in near-surface shallow trenches, usually in their shipping containers. There is no intent to recover the wastes once they are buried. There were once six operating commercial facilities in the United States licensed to bury LLRW. Now, only Hanford, Washington, and Barnwell, South Carolina are receiving waste for burial. The two currently operating commercial burial grounds are located in Agreement States and are regulated by the states. However, the NRC licenses special nuclear material because the quantities received by the commercial operator exceed those that the Agreement States may license under their agreements. The sites are all commercially operated.

10 CFR 61 of the NRC's regulations set forth the procedures, criteria, terms and conditions for licensing sites for land disposal of LLRW. These requirements also provide the basis for Agreement State regulation, since state rules must be compatible with NRC requirements.

7.4 Collection and Storage

Radioactive waste must be collected into designated receptacles in the laboratory, depending on the type of waste.

7.4.1 Plexiglass Boxes

The primary containers for collection of dry solid radioactive waste in the laboratory are plexiglass boxes (bins) that are built into the laboratory cabinets at the end of the work bench. The boxes are lined with thick, yellow-striped, clear plastic bags.

7.4.2 Waste Cans

All laboratories that produce solid radioactive waste must be provided with a clearly labeled radioactive waste can. Each can

should be lined with a yellow plastic waste bag. The bag should be labeled to show the radionuclides present in the waste, the dates of waste accumulation, and the laboratory in which it was generated. When the solid waste bags are filled, or if the exposure rate at the surface of the waste can exceeds 0.25 milliroentgen per hour (mR/h), the RSO should be contacted to remove the waste from the laboratory.

7.4.3 Liquid Waste

It is recommended that liquid waste be collected in polyethylene bottles (4 to 20 liters in size) whenever feasible. Unlike glass bottles, these are unbreakable, produce less secondary radiation, are impervious to most organic chemicals, and do not form sharp edges when compacted.

7.4.4 Liquid Scintillation Cocktails and Animal Carcasses

Liquid scintillation cocktails and animal carcasses containing hydrogen-3 and carbon-14 which fall below NRC *de minimis* level of 0.05 microcuries per gram (μCi/g) should be separated from other *non-de minimis* wastes. There are generally other, lower cost disposal options for these *de minimis* wastes.

7.4.5 Recordkeeping

A logsheet must be attached to each bin or step-can for scientific staff to enter the following disposal data:

- Isotope
- Amount of activity
- Users' initials
- Disposal date

Waste generated in the laboratory must be segregated and disposed of according to physical form and radionuclide. All radio-active material caution tape, as well as signs and labels, must be obliterated or defaced prior to deposit in the appropriate waste receptacle.

In deciding which waste receptacle to deposit waste contaminated with two or more radionuclides, the material must be disposed of according to the longest-lived component. Generally, hydrogen-3 and carbon-14 may be disposed of in the same waste container.

When emptying a radioactive waste receptacle:

- Remove the bag from the waste receptacle.
- Visually inspect waste for sharp items and radiation warning labels.
- Mark the bag with the radioisotope.
- Place the bag in a totally-enclosed lucite cart that is wheeled between laboratories and augmented with lead shielding when required.

The cart should then be transported to the nearest radioactive waste handling room for processing or temporary storage.

7.5 Transportation and Disposal

The waste producer is required to provide documentation of the identity and estimated quantity of radioactivity, and to ensure that the waste is properly labeled and contained. Each package of radioactive material, unless excepted, must be labeled on two opposite sides with a distinct warning label. The purpose of the

label is to alert personnel that the package contains radioactive materials and that special handling may be required. The determination of the proper label to use is based on the criteria contained in 49 CFR 172.403.

Radiation surveys should be conducted for each container to determine the external radiation levels and to detect possible surface contamination. Radiation limits for the external dose rate and removable surface contamination on packaging have been established by the DOT and can be found in 49 CFR 173. If survey results are within these regulatory limits, the waste container may be prepared for transportation to a waste disposal area. Waste brokers accept packed waste drums and transport them to a final disposal site.

7.5.1 Waste Storage

Radioactive waste in storage must be housed in rooms exclusively dedicated for this purpose. These rooms should be located in areas of the laboratories designed for low traffic, secured against unauthorized entry when not continuously attended, and monitored by surveillance equipment and security staff during non-business hours.

Radioactive waste held for decay-in-storage or interim storage must be processed in accordance with ALARA techniques (as discussed in Chapter C6 of this manual) and in anticipation of ultimate disposition.

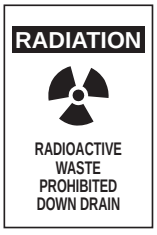
Solid wastes should be stored on-site in 55-gallon drums until a sufficient volume has accumulated for a radioactive waste shipment to a licensed low-level radioactive waste disposal facility. The contents of the drums must meet NRC and DOT regulations, as well as the requirements of the low-level waste disposal facility.

7.5.2 Discharge

Discharge of small quantities of liquid radioactive waste is allowed by the NRC in specifically designated laboratory sinks. The liquid radioactive waste must:

- Be readily soluble or dispersible in water
- Not contain chemically or biologically hazardous components

The average concentration disposed of in this manner must not exceed the limits specified in Appendix B of 10 CFR 20. These limits, which must be posted on each designated sink, are the maximum daily average quantities that may be disposed of into the laboratory drain. A record of the nuclide, quantity disposed, and date of disposal should be recorded on a logsheet that is collected by radiation safety staff.



If a liquid waste cannot be disposed of by discharge to the sanitary sewer, it may be precipitated and dried or evaporated, and treated as a solid waste.

7.5.3 Decay-in-Storage (DIS) Program

An EPA laboratory may be licensed to perform DIS until the activity decays if the radionuclide is short-lived. The NRC considers that materials with half-lives under 65 days may be managed by storage-for-decay. The NRC may also consider storage-for-decay for isotopes with

half-lives greater than 65 days on a permit-by-permit basis. These options may be im-practical if the half-life is greater than about 30 days.

After a storage interval of 10 half-lives, the waste should be surveyed at the container surface with a pancake Geiger-Mueller (GM) survey meter. If no activity above background is observed, the waste may be disposed of as nonradioactive. This waste, now deemed "cold," is generally disposed of via shredding and shipment to a landfill, or incineration.

7.5.4 Extended Interim Storage

Radioactive waste not suitable for decay-in-storage must be prepared, processed, and stored pending transfer off-site. This waste is further processed (via supercompaction or incineration) and ultimately land-buried. Generally, radio-active waste containing hydrogen-3 and carbon-14 should be handled in this manner. This method of storage must also be licensed by the NRC or an NRC Agreement State.

7.5.5 Radioactive Waste Minimization

Radioactive waste minimization involves treatment and processing techniques to either reduce the volume generated or to render the waste nonhazardous (i.e., no longer radioactive). Where practical, the following techniques should be used to minimize the generation of radioactive waste:

- Use nonradioactive alternatives.
- Substitute radioactive material with shorter half-lives (e.g., P-33 for S-35).
- Share and reuse radioisotope source vials that come in larger-than-required quantities (e.g., stock a supply of millicurie quantities for multiple users) or pay the extra cost for the smaller quantity that is generally regarded as a custom order.
- Plan and practice experimental procedures in advance to ensure that nonradioactive items are not inadvertently contaminated.
- Use reusable spill trays instead of layers of absorbent paper to define and protect the work area.
- Wear reusable protective clothing, such as cotton laboratory coats that are laundered instead of discarded as waste.
- For large items that are partially contaminated and cannot be sufficiently cleaned, cut out and dispose of only the contaminated portion as radioactive waste.
- Decontaminate plastic plates, tips, and glassware by soaking the items in a mixture of detergent for a few days to render the waste nonradioactive. The cleaning solution can then be disposed of via the sanitary sewer system.
- Carefully segregate leftover reagents, boxes, and packing material and dispose of them as nonradioactive.

The approximate amount of radioactive waste generated in a given period should be quantified, with results tracked for waste minimization purposes.

7.6 Mixed Waste

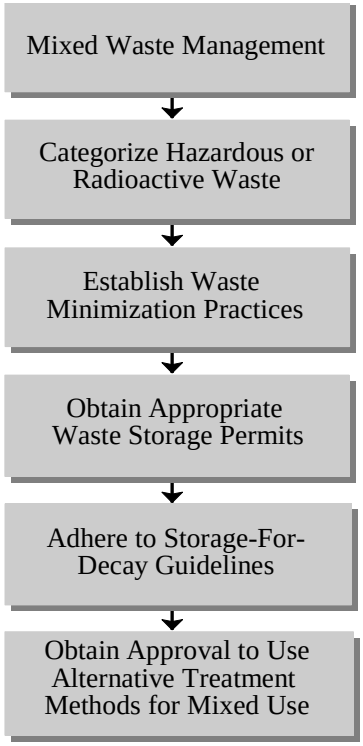
Some EPA laboratories may generate mixed waste, or waste containing both hazardous waste and source, special nuclear, or byproduct radioactive material. Such laboratories must satisfy the requirements of both the NRC regulations under the AEA and the EPA regulations under RCRA.

7.6.1 Radioactive Components

The radioactive component of mixed wastes is classified as LLRW. Any class of radio-active waste that contains a hazardous waste, as defined in RCRA, is considered mixed waste. Categories of radioactive mixed waste include liquid scintillation fluid (LSF), waste oil, chlorinated fluorocarbons, cadmium, lead, mercury, and aqueous corrosives. The liquid scintillation counting (LSC) fluids category is the largest mixed waste generated by EPA laboratories. LSC fluids usually contain toluene and xylene, and may sometimes contain benzene or pseudocumene.

7.6.2 Mixed-Waste Management Program

The NRC and the EPA require mixed-waste generators to establish a mixed-waste management program that includes the following elements:



7.6.3 Source Reduction and Avoidance Management

Types of source reduction and avoidance management activities that can be implemented for mixed wastes include the following:

- Substitution and/or use of biodegradable solvents
- Waste segregation and separation
- Process modifications
- Recycling
- Storage-for-decay
- Administrative controls

Additional information on mixed waste can be found in the EPA SHEM Guide 41.

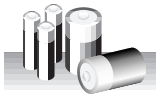
8.0 Special Waste

"Special waste" refers to wastes that are neither nonhazardous nor hazardous. These wastes are usually considered "industrial wastes." Specific state regulations must be applied to, and followed in, the management of such wastes.

8.1 Identification and Inventory

Types of special wastes that, depending on the individual laboratory's state of residence, may be present at EPA laboratories include (but are not limited to) the following:

- Contaminated soils
- Grinding dusts
- Asbestos
- Waste oils
- Antifreeze
- Dried paint wastes
- Wastewater treatment sludges
- Batteries



The approximate amount of special waste generated in a given period should be quantified, with results tracked for waste minimization purposes.

8.2 Characterization

Prior to categorizing wastes as special wastes, many states require that wastes are evaluated and determined to be nonhazardous.

8.3 Applicable Regulations

Special wastes are regulated at the state level. As such, an all-inclusive list of these wastes does not exist. States that have special waste regulations include, but are not limited to, the following:

- Connecticut
- Florida
- Illinois
- Massachusetts
- Washington

8.4 Collection and Storage

General special waste collection and storage practices that should be followed at EPA laboratories include:

- Storing special wastes in an environmentally safe manner.
- Ensuring that containers are in good condition (e.g., not leaking, container materials compatible with waste contained within, etc.)
- Reporting any special waste spills to the regulating agency, as appropriate.

Specific state regulations should be consulted for additional collection and storage requirements.

8.5 Transportation and Disposal

General special waste transportation and disposal practices that should be followed at EPA laboratories include:

- Using manifests when transporting special wastes for treatment and/or disposal, if required
- Using licensed transporters for shipping special wastes
- Disposing of special wastes only at facilities that are licensed in accor-

dance with the requirements of the state where the disposal facility is located

- Selecting and using appropriate disposal options (e.g., landfilling)

Specific state regulations should be consulted for additional transportation and disposal requirements.

9.0 PCB Waste

This section establishes prohibitions of, and requirements for, the use, disposal, storage, and marking of polychlorinated biphenyls (PCBs) and PCB items (i.e., any PCB-containing article, article container, container, or equipment that deliberately or unintentionally contains PCBs).

Most of the federal provisions apply to PCBs only if PCBs are present in concentrations above a specified level (e.g., at or above 50 ppm). No provision specifying a PCB concentration may be avoided as a result of any dilution, unless otherwise specifically provided in applicable regulations. Refer to Chapter C15 of this manual for more information on the regulation and management of PCBs.

9.1 Identification and Inventory

Regulated substances that may be present at EPA laboratories include, but are not limited to, the following:

- Dielectric fluids
- Contaminated solvents
- Oils and waste oils
- Heat transfer fluids
- Hydraulic fluids
- Paints
- Sludges and slurries
- Dredge materials
- Soils
- Materials contaminated as a result of spills
- Other chemical substances or combination of substances

The approximate amount of PCB waste generated in a given period should be quantified, with results tracked for waste minimization purposes.

9.2 PCB Waste Characterization

If a waste solution, mixture, or material is known or suspected to be contaminated with PCBs, such items must be characterized as PCB-containing (greater than or equal to 50 ppm PCBs) or as non-PCB-containing (less than 50 ppm PCBs) prior to transportation and/or disposal.

9.3 Applicable Regulations

Federal regulations for the handling, storage, disposal, and reporting of materials containing PCBs in concentrations greater than 50 ppm are regulated under the Toxic Substances Control Act (TSCA). Applicable regulations are listed in 40 CFR 761.

Because states may have additional PCB regulations, EPA laboratories should consult their specific state regulations for more information.

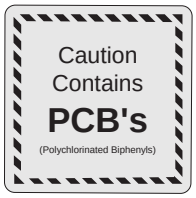
9.4 Collection and Storage

Proper PCB waste collection and storage includes specific marking and storage requirements as well as the development of specific spill prevention, control, and

countermeasure practices.

9.4.1 Marking Requirements

Any container holding PCBs in a concentration greater than 50 ppm must be marked with a label stating:



[Note: Any container, piece of equipment, article, etc., determined to have PCBs in concentrations less than 50 ppm should be marked with a label that reads, "This (container, equipment, article, etc.) does not contain PCBs."]

9.4.2 Storage

Containers used for the storage of wastes containing PCBs in concentrations greater than or equal to 50 ppm must comply with the following DOT container specifications:

- Label the container with a PCB label.
- Mark the container with the date when the waste was first added.
- Maintain secondary containment and a running inventory that lists the date and amount and type of material being accumulated.

Wastes with PCBs in concentrations less than 50 ppm should be placed in a polybottle or smaller container (if possible). The container should be marked with the same requirements as previously mentioned for wastes containing PCBs in concentrations greater than or equal to 50 ppm.

Any PCB container designated for disposal must be removed from temporary storage within 30 days and disposed of within one year from the date it was first placed in storage.

Waste storage areas must be provided with the following:

- Adequate roof and walls to prevent rainwater from reaching the stored PCBs and PCB items
- An adequate floor that has a continuous curb at least six inches high and that provides a containment volume equal to at least two times the internal volume of the largest PCB article or PCB container stored therein, or 25 percent of the total internal volume of all PCB articles or PCB containers stored therein, whichever is greater
- A floor designed without drain valves, floor drains, expansion joints, sewer lines, or other openings that would permit liquids to flow from the curbed area
- Floors and curbing constructed of continuous smooth and impervious materials, to prevent or minimize penetration of PCBs

In addition, storage areas must not be located at a site that is below the 100-year flood water elevation.

9.4.3 Spill Prevention, Control and Countermeasure (SPCC) Plan

EPA laboratories that generate PCB wastes during the course of laboratory analyses must ensure that their SPCC

plans address the following:

- Securing all PCB-containing materials in a closed primary container with secondary containment
- Ensuring that measures are in place to arrest the spread of a spilled material, to clear personnel from the immediate area of the spill, and to notify the appropriate emergency coordinator
- Providing absorbent material to clean up spills that occur outside the secondary containment
- Placing spill cleanup materials in PCB waste containers and disposing of containers in accordance with applicable regulations
- Decontaminating all surfaces contaminated by spilled PCB-containing materials by triple rinsing with a suitable solvent (e.g., acetone)
- Disposing of all used decontamination materials as contaminated PCB waste
- Activating the laboratory hazardous waste contingency plan in the event of a spill/release of PCB-contaminated materials that has the potential to damage human health or the environment. Chapter C13 of this manual provides specific guidance on SPCC programs

9.5 Transportation and Disposal

All PCB waste materials should be transported off-site to an approved waste management facility. In addition, all PCB waste materials should be disposed of in accordance with the practices in Table C14-3. Records of all PCB waste transports and/or disposals should be maintained.

Table C14-3: PCB Waste Disposal Practices

PCB Waste Type	Disposal
Materials contami-nated with PCBs of concentrations <50 ppm	Permitted hazardous waste treatment facility
PCBs at concentrations ≥50 ppm	Approved incinerator at a permitted PCB disposal facility
Spills and other uncontrolled PCB discharges at concentrations ≥50 ppm	Incineration
PCB containers with PCB concentrations ≥500 ppm	Incineration
Any PCB container used to contain only PCBs at a concentration <500 ppm	Municipal solid waste disposal

Attachment C14-1: Hazardous Waste Drum Storage Area Inspection Checklist

Purpose: To provide an example of an inspection checklist for a hazardous waste drum storage area.

Instructions: Use this checklist when inspecting hazardous waste storage areas to help determine if storage practices are consistent with regulatory requirements.

Hazardous Waste Drum Storage Area Inspection Checklist			
Date:	Hazardous Waste Drum Storage Area:		
Inspector:			
Question		**Yes**	**No**
Container Condition			
Is the area free from evidence of leaks and spills?			
Are all containers securely closed?			
Are all containers marked with the words “Hazardous Waste,” the waste description, and the date of accumulation?			
Are all container dates within the allowed accumulation time frame?			
Are all containers free from signs of corrosion or evidence of bulging?			
Container Arrangement			
Is aisle space sufficient for inspection of all containers?			
Are labels on all containers readable?			
Are containers properly positioned (i.e., not stacked more than two high, etc.)			
Are containers with different labels properly separated?			
Can emergency equipment access the area?			
Containment			
Is any accumulated precipitation free from evidence of leaks and spills?			
Are the floor and containment devices free from cracks and other deficiencies?			
Is the drain valve locked in the closed position?			
Emergency Equipment			
Is the emergency equipment cabinet fully stocked, as per the inventory list?			
Is the communication device nearby and functioning?			
Are notification procedures posted near the communication device?			
Are fire extinguishers readily available?			
Are warning signs clearly visible?			
Note: *Immediately report any “NO” answers to your supervisor.*			

Attachment C14-2: Waste Minimization Techniques

Purpose: To evaluate current waste minimization activities and provide guidance on how to perform more waste minimization.

Instructions: Answer the questions pertaining to current waste minimization. The questions that were answered "No" are areas that may need additional waste minimization.

Waste Minimization Techniques		
To reduce excess wastes, do you:	**Yes**	**No**
1. Buy and keep on hand only the amount of raw material needed?		
2. Use recyclable materials when possible?		
3. Use raw materials sparingly so that excess waste is not generated?		
4. Use raw materials in correct proportions so that excess waste is not generated by making defective products/formulations?		
5. Ensure that all containers free from signs of corrosion or evidence of bulging?		
6. Check for faulty valves/pipes to ensure that the product is not being lost from the system or unintentionally contaminated?		
7. Ensure that all products and wastes are inventoried, clearly labeled, and properly stored?		
8. Segregate wastes to assess the potential for recycle, reuse, or resale of the wastes?		
9. Substitute any nonhazardous products for hazardous materials?		
10. Use only as much of a hazardous substance as a job requires?		
11. Use an entire product (rather than throw away partially filled containers)?		
12. Use existing materials more efficiently (i.e., make double-sided photocopies)?		
13. Encourage the use of technological changes (e.g., changes in the production process, use of automation, etc.) that reduce wastes/eliminate inefficiencies, enhance recovery of recycling options, increase product yields, and decrease probability of error?		
14. Check the optimum settings for certain parameters (i.e., flow rates, residence times, temperatures, pressures)?		
15. Refrain from mixing hazardous wastes with nonhazardous/different wastes?		
16. Use waste concentration/water conservation to minimize hazardous waste generation?		
17. Avoid producing/transferring spills and leaks?		
18. Conserve energy?		

Attachment C14-3: Hazardous Waste Accumulation Area Inspection Checklist

Purpose: To provide an example of a checklist that can be used to inspect hazardous waste accumulation areas.

Instructions: Answer the questions based on observations at a hazardous waste accumulation area. Any questions that are answered "No" should be addressed immediately.

HAZARDOUS WASTE ACCUMULATION AREA

INSPECTION CHECKLIST

DATE:	INSPECTED BY:
BUILDING:	ROOM:

		YES	NO
1.	Are the areas free of evidence of leaks or spills?		
2.	Are all containers securely closed?		
3.	Are containers free of signs of corrosion, leaks, or other deterioration?		
4.	Are containers compatible with the hazardous waste stored in them and do they meet DOT standards?		
5.	Is there adequate aisle space?		
6.	Are containers handled in a safe way as to prevent leaking or rupture?		
7.	Are hazardous waste labels present, visible, and readable?		
8.	Are Accumulation Start Dates present, visible and readable?		
9.	Are incompatible wastes placed in the different containers?		
10.	Is the required emergency equipment present?		
11.	Is the required communication device present and functioning?		
12.	Are notification instructions posted near the communication device?		

Remarks:

_____

_____

_____

Signed: _____ Inspector	Reviewed By: _____ Date: _____

1.0 Introduction

The Toxic Substances Control Act (TSCA) is intended to ensure that "new" chemical substances are appropriately evaluated before they are introduced into commerce in the United States; to collect information on chemicals that are already in use; and to control the manufacture, processing, distribution, use, storage, and disposal of particular categories of toxic substances (most particularly polychlorinated biphenyls [PCBs]). Major provisions of TSCA include:

- Development and maintenance of a master inventory of all "existing" chemical substances in commerce in the United States
- Specification of notification requirements for the manufacture, importation, or processing of "new" chemical substances (i.e., those not already on the TSCA inventory)
- Requirements for gathering safety and environmental data for specific chemicals if the EPA laboratory determines that they may pose an unreasonable risk of injury, or when there is potential for significant environmental or human exposure
- Regulation of existing chemicals (including prohibition or limitation of production) if the laboratory determines that they pose an unreasonable risk of injury to health or the environment
- Prohibition of and requirements for the manufacture, processing, distribution in commerce, use, disposal, storage, and marking of PCBs and PCB items

TSCA applies to United States federal government agencies, to state and local government agencies, and to private business entities. However, virtually all sections of TSCA apply only to those entities (private or public sector) that manufacture, import, process, or distribute chemical substances for commercial purposes. Since EPA laboratories are not-for-profit entities, their activities do not generate commercial advantage either for the laboratory or for the agency as a whole. Therefore, they are not subject to most TSCA requirements that relate to "new" chemical substances introduced into commerce.

In contrast to the TSCA requirements for "new" chemicals, which apply only to those entities that manufacture, import, or process the substances, the PCB requirements (40 CFR 761) also apply to any entity that *uses, disposes of, or stores* PCBs or PCB items. Two possible scenarios under which EPA laboratories could be subject to TSCA requirements are listed below:

- The laboratory uses small quantities of PCBs for research and development purposes, including use as analytical standards.

- The laboratory's infrastructure incorporates PCB-contaminated electrical equipment, PCB transformers, or PCB-containing items such as fluorescent light ballasts.

In addition to the PCB scenarios above, the following activities involving "new" chemical substances, if undertaken on the laboratory's behalf, could trigger some TSCA obligations:

- Serving as the importer of record for a new-to-the-United States chemical substance
- Exporting specific chemicals

EPA Program Requirements

To ensure that requirements are met under the TSCA, EPA laboratories must:

- Determine the applicability of the TSCA's regulations, which are outlined in the Table C15-1.
- Label TSCA-regulated materials.
- Store and dispose of applicable materials as regulated.
- Maintain related records

Program Administration

To effectively manage a program addressing TSCA requirements, responsibilities should be assigned for:

- Determining the applicability of TSCA requirements to the laboratory
- Providing appropriate labeling on applicable materials
- Ensuring proper storage and disposal of applicable materials
- Reporting and cleaning spills of applicable materials

Table C15-1: Toxic Substances Control Requirements

Regulations	Key Requirements	Exemptions exist? (Y/N)	Key Characteristics/Feature(s)	Chapter 16 Section/ CFR References
TSCA Inventory	Reporting	Y	Small quantities for research and development (R&D) exemption	16.2/40 CFR 710
Premanufacture Notice	Reporting	Y	Exempt if: • Small quantities for R&D • Employees notified of potential health risks • Technically qualified supervisor uses the substance	16.3/40 CFR 720
Significant New Use Rule (SNUR)	Reporting	Y	Same exemption criteria as those for Premanufacture Notice	16.4/40 CFR 721
Preliminary Assessment Information Rules (PAIR)	Reporting	Y	Exempt if chemicals are used solely for scientific experimentation, analysis, or R&D.	16.5/40 CFR 712
Allegations	Recordkeeping and Reporting	N	Laboratories must maintain records for employee allegations of adverse reaction(s) to chemicals.	16.6/40 CFR 717
Reporting Health and Safety Studies	Reporting	N	• Unpublished studies for listed substances must be submitted to the EPA. • Exemptions exist only for certain studies.	16.7/40 CFR 716
Notice of Substantial Risk	Reporting	N	Laboratories must notify the EPA of any new substantial risk regarding chemicals or mixtures.	16.8/40 CFR 717
Imports/Exports		Y: Importing N: Exporting	Exempt from Importing Notification requirements if the exemption criteria for Premanufacture Notice are met	16.9/40 CFR 707
Chemical-Specific Test Rules		N	Laboratories must submit certain data for chemicals or mixtures listed in Subpart B for a given testing period.	16.10/40 CFR 799
PCB Management	Labeling and storage of PCB-containing equipment	Y	Exemptions exist for: • PCB concentrations < 50 ppm • Small quantities for R&D	16.11.2/40 CFR 761
PCB Disposal	Notification and recordkeeping	N	• PCB wastes > 50 ppm must be incinerated. • Receiving facility must be approved for specific waste being shipped.	16.11.3/40 CFR 761
PCB Spill	Procedures for responding to a PCB spill	N	Specific requirements exist for spills of materials containing PCBs with concentrations > 50 ppm.	16.11.4/CFR 761.120
PCB Records	Recordkeeping and reporting	N	• Labs with a Class Exemption must retain PCB records for five years. • Labs processing/distributing more than 22 lbs. of PCBs for R&D in one year must notify the EPA.	16.11.5/40 CFR 761

2.0 Import of "New" Chemical Substances

If an EPA laboratory imports a chemical substance into the Customs territory of the United States, it must certify either that the substance is subject to TSCA and complies with all applicable requirements (positive certification) or that the substance is not subject to TSCA (negative certification). As long as the laboratory does not intend or expect to receive immediate or eventual commercial advantage from the substance, it is not subject to TSCA and the negative certification can be made. The certification should state:

"I certify that all chemicals in this shipment are not subject to TSCA."

3.0 Export of Chemical Substances

An EPA laboratory that intends to export a chemical substance must first determine whether any of the following actions have been taken under TSCA with respect to that chemical substance:

- Data are required under TSCA Section 4 or 5(b).
- An order has been issued under TSCA Section 5.
- A rule has been proposed or promulgated under TSCA Section 5 or 6.
- An action is pending or relief has been granted under TSCA Section 5 or 7.

There is no easy way of making this determination, and no accessible listing of substances for which such actions have been taken. The laboratory is advised to call the TSCA hot line (1-202-554-1404) or to use other resources available within the laboratory to make the determination.

For export to a particular country, if the chemical substance is subject to one of the TSCA actions listed above, the exporter of the substance must notify the EPA. Notification must take place within one calendar year and be postmarked within seven days of "forming the intent" to export, or on the date of export (whichever is earlier). The required contents of the notice are:

- Name of the regulated chemical
- Name and address of the exporter
- Country(ies) of import
- Date(s) of export or intended export
- The Section (4, 5, 6, or 7) of TSCA under which EPA has taken action

The notice, marked "Section 12(b) Notice," is sent to the TSCA Document Processing Center (TS-790), Office of Pollution Prevention and Toxics, EPA, 401 M Street, SW, Washington, DC, 20460.

4.0 Polychlorinated Biphenyls (PCBs)

EPA laboratories may use PCBs in small quantities for the purpose of research and development (R&D) indefinitely, provided that:

- Records of their PCB activities are maintained for a period of five years.

- Sites of PCB activities and the quantity of PCBs to be processed are reported to the EPA by laboratories that process more than 100 grams in a year.

"Small quantities for research and development" means PCBs, in sealed containers of no more than 5 milliliter volume, that are used for scientific experimentation or analysis, or for chemical research on PCBs. It does not include research and development (R&D) activities related to developing PCB products. Also, R&D on disposal methods using PCBs constitutes "disposal," under 40 CFR 761.60, and must comply with these regulations. Such disposal R&D requires approval from the EPA.

Most waste from R&D activities (e.g., used PCB standards, contaminated containers, contaminated laboratory equipment, etc.) is likely to contain less than 50 ppm of PCBs and its disposal is not specifically regulated under TSCA. However, if EPA laboratories' R&D activities generate PCB waste that contains 50 ppm or more of PCBs, they must use a disposal facility (incinerator) that is permitted to accept PCBs and has no outstanding TSCA violations. Refer to Chapter C14 of this manual for further discussion on disposal of PCBs.

4.1 PCB Survey and Labeling

EPA laboratories must survey their operations to determine whether they contain such items as:

- PCB-Transformers—Any transformers containing 500 ppm or more of PCBs

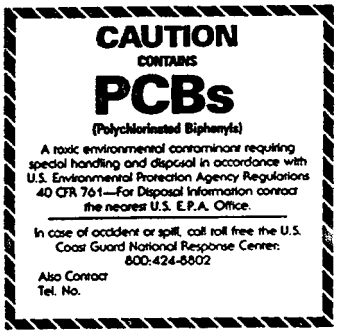
- PCB-Contaminated Electrical Equipment—Any transformers, capacitors, circuit breakers, voltage regulators, switches, etc., that contain between 50 and 500 ppm PCBs (Oil-filled equipment, other than circuit breakers, reclosers, and cable, whose PCB content is unknown, must be assumed to be PCB-contaminated electrical equipment.)

- PCB Containers—Any packages, cans, bottles, barrels, drums, tanks, etc., used to contain PCBs or PCB articles and whose surfaces have been in direct contact with PCBs.

- PCB Articles—Any manufactured articles, other than a PCB container, that contain PCBs and whose surfaces have been in direct contact with PCBs.

If any of the above are present on-site, they must be marked as illustrated in Figure C15-1. This label must also be used to mark areas used for storage of PCB items.

Figure C15-1: Label Example



4.2 Storage

PCBs, PCB items, and PCB cleanup debris over 50 ppm may be stored for up to one year prior to disposal. Items removed from service and awaiting disposal must be stored in areas that have:

- Adequate roof and walls to prevent infiltration of rainwater

- Adequate floors and curbing constructed of impervious material
- Secondary containment volume sufficient to hold two times the largest single container or 25 percent of the total
- No floor drains or other openings that would allow release of liquids from the curbed area

The location must be above the 100-year flood water elevation. (These requirements do not apply to temporary [up to 30 days] storage of PCB items that are non-leaking, overpacked, non-liquid, or liquids with less than 500 ppm PCBs.) PCB storage areas must be inspected at least every 30 days and records of the inspections must be maintained.

4.3 Spill Cleanup

Spill requirements vary according to the size of the spill and the nature of the receptor. Spills of more than 10 pounds of PCBs or any spill that directly contaminates surface water, sewers, drinking water supplies, grazing lands, or vegetable gardens must be reported to the EPA Regional Office of Prevention, Pesticides, and Toxic Substances Branch in the shortest possible time, but never later than 24 hours after discovery. Spills of less than 10 pounds do not need to be reported, but must be decontaminated within the shortest possible time after discovery. In summary, decontamination procedures require:

- Cordoning off the affected area
- Recording and documenting the area of visual contamination
- Initiating cleanup of all visible traces
- Cleaning of all indoor surfaces to 10 $\mu g/100\ cm^2$, outdoor surfaces to 100 $\mu g/100\ cm^2$, and soil cleaned to 25 ppm PCBs by weight

This assumes that the spill occurs within a restricted access area (the laboratory property). Other, stricter requirements apply if the spill reaches areas where people live or work.

In addition, all other applicable reporting requirements under the Clean Water Act and the Comprehensive Environmental Response, Compensation and Liability Act must be met. For example, all spills involving 10 pounds or more by weight of PCBs must be reported to the National Response Center (1-800-424-8802). For additional emergency response information, refer to Chapter G2 of this manual.

4.4 Recordkeeping

Laboratories that use or store, at any one time, at least 45 kilograms (99.4 pounds) of PCBs in containers, one or more PCB transformers, or 50 or more PCB large (more than 3 pounds of dielectric fluid) capacitors must maintain records and a written annual document log. The annual records must include all manifests and all Certificates of Disposal received by the facility during the year. The written document log must include the following:

- The name, address, and EPA identification number of the laboratory
- The calendar year covered by the log
- The unique number of every manifest generated during the year

- For PCB items (transformers, capacitors, PCB containers, etc.), transported off-site
  - — A unique identifying number
  - — A description of the contents (for containers)
  - — The total weight (kilograms) of PCB in each item
  - — The date the item (or contents) was destined for disposal
  - — The date the item was transported off-site
  - — The date of disposal (if known)

- For PCB items in service or storage on-site:

  - — The total number of items and the total weight (kilograms) of PCBs in articles (capacitors or transformers) and containers placed in storage for disposal during the calendar year

  - — The total number of PCB transformers in service at the end of the year and the total weight (kilograms) of PCBs in them

  - — The total number of large PCB capacitors in service at the end of the year and the total weight (kilograms) of PCBs in them

  - — The total weight (kilograms) of PCBs in containers remaining in service at the end of the year.

- A record of each telephone call or other method used to confirm receipt of PCB waste transported by an independent transporter

1.0 Introduction

The regulations pertaining to underground storage tanks (USTs) are designed to prevent spills from overfilled or leaking tanks. The following guidance will assist in the management of USTs and UST systems in accordance with the requirements under the U.S. Resource Conservation and Recovery Act (RCRA).

EPA Program Requirements

To ensure that requirements for USTs are met, EPA laboratories must:

- Ensure that tank designs meet applicable regulations
- Report, investigate, and clean up any spills
- Submit required reports to the implementing regulatory agency

Program Administration

To effectively manage a UST program, responsibilities should be assigned for:

- Determining if regulations are applicable to the facility
- Ensuring any new tanks meet design requirements for USTs
- Determining what upgrades may be necessary on existing tanks
- Providing monitoring for transfer operations
- Inspecting UST systems
- Submitting reports and maintaining required records

2.0 Applicability of Requirements

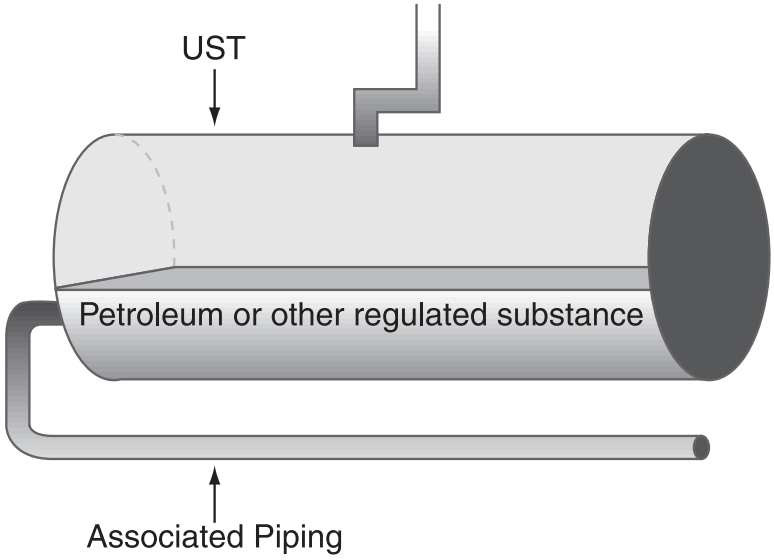
A UST is subject to the regulatory requirements found in 40 CFR 280 except:

- UST systems holding hazardous wastes listed, or identified, under Subtitle C of the Solid Waste Disposal Act, or a mixture of such hazardous wastes and other regulated substances
- Wastewater treatment tank systems that are part of a wastewater treatment facility regulated under Section 402 or 307(b) of the Clean Water Act
- Equipment or machinery that contain regulated substances for operational purposes (e.g., hydraulic lift tanks and electrical equipment tanks)
- USTs with a capacity of 110 gallons or less
- USTs that contain a *de minimus* concentration of regulated substances
- Emergency spill or overflow containment UST system that is expeditiously emptied after use

UST exemptions vary from state to state. Specific state regulations for USTs must be consulted to determine requirements.

3.0 Design and Construction

The regulations define *new tanks* as USTs under construction after December 22, 1988. All other USTs are considered *existing tanks*. The following sections describe the design and construction of both new and existing USTs.



3.1 New USTs

In order to conform with requirements for new USTs, EPA laboratories must:

- Submit notification forms to the State agency certifying the proper installation of the UST
- Implement procedures and use devices to prevent releases from USTs
- Design and construct USTs and associated piping with corrosion protection
- Check USTs monthly for releases using approved methods

3.1.1 Installation, Certification, and Notification

When a new UST is installed at an EPA laboratory, the laboratory must submit a notification form certifying one of the following:

- The installer has been certified by the tank and piping manufacturers or by the implementing agency
- The installation has been inspected and certified by a registered professional engineer
- The installation has been inspected and approved by the implementing agency (i.e., EPA or designated state/local agency)

An example notification form is provided in Attachment C16-1.

3.1.2 Release Protection

As an owner and operator of a new UST, EPA laboratories must prevent releases resulting from USTs by:

- Following proper filling procedures and ensuring available tank volume prior to transfer
- Monitoring transfer operations using electronic or mechanical means
- Use devices such as catchment basins and automatic shut-offs

3.1.3 Corrosion Protection

The EPA must also ensure that tanks and piping for new USTs are designed and constructed in a way that protects them from corrosion. Several methods available include the use of cathodic protection, noncorrodible material, steel with fiberglass reinforcement, or alternate methods. Each are described in the following sections.

Cathodic Protection

The tank and piping are coated with a corrosion-resistant material. Sacrificial anodes or impressed current are used to reverse the electric current associated with corrosion.

All UST systems equipped with cathodic protection systems must be inspected for proper operation by a qualified cathodic protection tester in accordance with the following requirements:

- Test within six months of installation and at least every three years, or according to another reasonable time frame established by the implementing agency.
- Ensure the criteria that are used to determine if cathodic protection is adequate must be in accordance with a code of practice developed by a nationally recognized association.

UST systems with impressed current cathodic protection systems must also be inspected every 60 days to ensure the equipment is running properly.

Noncorrodible Material
Tanks and piping are constructed of a material not susceptible to corrosion (e.g., fiberglass).

Steel with Fiberglass Reinforcement
Steel tanks have a layer of noncorrodible material bonded to the outside.

Alternate Method
Other protection methods may be used if approved by the implementing regulatory agency.

3.1.4 Leak Detection

UST systems must be provided with a method, or combination of methods, of release detection as shown in Figure C16-1, that:

- Can detect a release from any part of the tank and the underground piping that routinely contains product

- Is installed, calibrated, operated, and maintained in accordance with the manufacturer's instructions, including routine maintenance and service checks for operability or running condition

- Meets the performance requirements in 40 CFR 280.43 or 40 CFR 280.44, with any performance claims and their manner of determination described in writing by the equipment manufacturer or installer and meeting regulatory performance standards for sensitivity

EPA laboratories must check new USTs monthly for releases using one or more of the following methods:

- Inventory control
- Vapor monitoring
- Manual tank gauging
- Groundwater monitoring
- Tank tightness testing
- Interstitial monitoring
- Automatic tank gauging
- Other method approved by regulatory authority

Some tanks are exempt from these requirements. Examples are presented below.

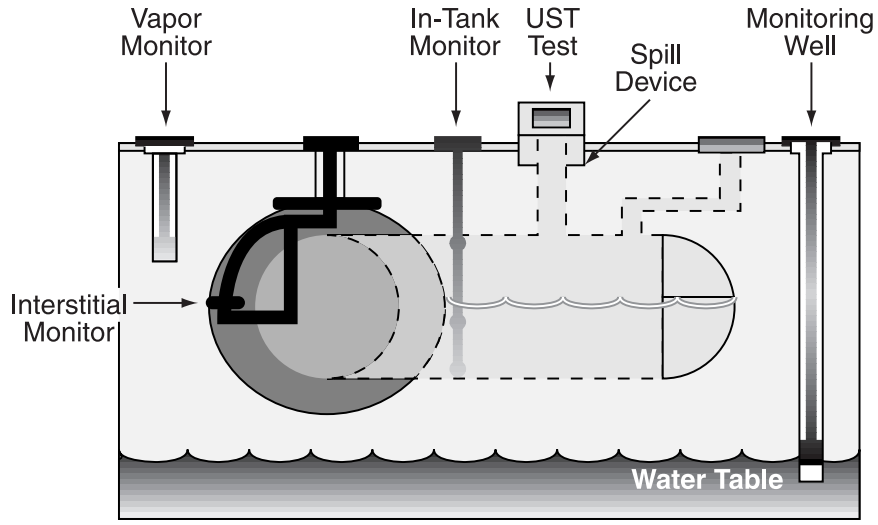
- UST systems that meet the performance standards in 40 CFR 280.20 or 280.21, and the monthly inventory control requirements in 40 CFR 280.43(a) or (b), may use tank tightness testing at least every five years until December 22, 1998, or until 10 years after the tank is installed or upgraded, whichever is later.

- UST systems that do not meet the performance standards in 40 CFR 280.20 or 280.21 may use monthly inventory controls and annual tank tightness testing until December 22, 1998 when the tank must be upgraded or permanently closed.

- Tanks with capacity of 550 gallons or less may use weekly tank gauging.

Underground piping that conveys regulated substances must either have a line tightness test conducted at least every three years, or use a monthly monitoring method conducted in accordance with 40 CFR 280.44(c). No release detection is

Figure C16-1: UST Leak Detection



required for suction piping that is designed and constructed to meet the following standards:

- Below-grade piping operates at less than atmospheric pressure
- Below-grade piping is sloped so that the contents of the pipe will drain back into the storage tank if the suction is released
- One check valve only is included in each suction line
- The check valve is located directly below, and as close as practical to, the suction pump
- A method is provided that allows compliance with paragraphs 40 CFR 280.41(b)(2)(ii)-(iv) to be readily determined

3.2 Existing UST Systems

USTs and piping installed before December 1988 are subject to the same requirements as newer USTs, but with a different timetable for compliance.

As of December 22, 1998, existing USTs must be closed unless they meet the system performance standards (i.e., corrosion protection for steel tanks and piping, spill and overfill [release] prevention, equipment leak detection), or internal lining or cathodic protection upgrade requirements.

3.2.1 Internal Lining

A tank may be upgraded by internal lining if the lining is installed in accordance with the requirements of 40 CFR 280.33. Within 10 years after lining the UST, and every five years thereafter, the lined tank must be internally inspected and found to be structurally sound.

3.2.2 Cathodic Protection

A tank may be upgraded using cathodic protection that meets the requirements of 40 CFR 280.21 if one of the following apply:

- Internal inspections and assessments have be performed to ensure that the tank is structurally sound and free of holes prior to installing the cathodic protection system

- The tank has been installed for less than 10 years and has been monitored monthly for releases in accordance with 40 CFR 280.43(d) through (h)

- The tank has been installed for less than 10 years and is assessed for holes by conducting two tightness tests. The first tightness test must be conducted prior to installing the cathodic protection system. The second tightness test must be conducted between three and six months following the first operation of the cathodic protection system

- The tank is assessed for corrosion holes using a method that is approved by the implementing agency

Upgrading by combining internal lining and cathodic protection is acceptable if requirements in 40 CFR 280.33 and 281.21 are met. Existing USTs must comply with leak detection requirements for new USTs as required by the phased-in schedule in Table C16-1.

Table C16-1: Leak Detection Requirements

Year Installed	Must have leak detection by December 22 of...				
	1989	1990	1991	1992	1993
Before 1965 or date unknown	P	P			
1965-1969		P/RD			
1970-1974		P			
1975-1979		P	RD		
1980-1988		P		RD	

P = pressurized piping
RD = release detection

4.0 Inventory

Laboratories should develop a formal process for inventory control by conducting regular measurements of each USTs contents. These measurements should be recorded daily on a UST reconciliation form to keep track of withdrawals from, and deliveries into, the UST. Refer to Attachment C16-2 for an example Underground Storage Tank Daily Reconciliation Form.

A certain amount of variation is acceptable depending on the product, water in the tank, and amount of products removed or delivered. If records reveal continued shortages, a leak investigation should be conducted. Sources of potential discrepancies may include:

- Fuel pump meter calibration error
- Discrepancy of delivery
- Temperature variations
- Measurement error
- Pilferage

Investigation guidance is included in Table C16-2. If the discrepancy is not associated with the above problems, a leak is likely. If leaks are detected, laboratories should ensure that they are properly reported to facility personnel and the implementing agencies.

5.0 Recordkeeping and Reporting

Laboratories must maintain the following information, as applicable:

- A corrosion expert's analysis of site corrosion potential (if corrosion protection equipment is not in use)
- Documentation of UST system repairs
- Recent compliance with release detection requirements
- Results of the site investigation conducted at permanent closure

Table C16-2: Leak Investigation Procedures

Unexplained Loss From Reconciliation Over 30 days	Unexplained Loss From Two Successive Reconciliations
Step 1. Notify the people responsible for the maintenance of the equipment and carefully inspect the readily accessible physical facilities on the premises for evidence of leakage. ***Step 2.*** If Step 1 does not explain the loss, calibrate the pumps used with the particular product involved with the apparent loss. But, first fill a calibrated five-gallon can from each pump to determine if a pump calibration is required. ***Step 3.*** If Step 2 does not explain the loss, test the piping system between the storage tank and dispensers in an acceptable manner to determine if this segment of the system is leaking. If the tank has a remote fill and the variations occur at the time of filling, also test the remote fill line. ***Step 4.*** If Step 3 does not explain the loss, leak test the storage tank. ***Step 5.*** If Steps 1 through 4 do not explain the loss, continue the daily inventory with an independent verification by a qualified person. Also, conduct additional surveillance of the facility to ensure against unauthorized removal of the product.	***Step 1.*** Notify the people responsible for the maintenance of the equipment and carefully inspect the readily accessible physical facilities on the premises for evidence of leakage. ***Step 2.*** If Step 1 does not explain the loss, test the piping system between the storage tank and dispensers as well as the fill lines in an acceptable manner to determine if this segment of the system is leaking. ***Step 3.*** If Steps 1 through 3 do not explain the loss, continue additional reconciliations with an independent verification by a qualified person. Also, conduct additional surveillance of the facility to ensure against unauthorized removal of the product.

Laboratories with USTs must submit the following information to the implementing agency:

- Notification for all UST systems, which includes certification of installation for new UST systems
- Reports of all releases including suspected releases, spills and overfills, and confirmed releases
- Corrective actions planned or taken including initial abatement measures, initial site characterization, free product removal, investigation of soil and groundwater cleanup, and corrective action plan
- A notification before permanent closure or change-in-service

For UST systems using cathodic protection, records of the operation of the cathodic protection must be maintained to demonstrate compliance with the performance standards in this chapter. These records must provide the following:

- The results of the last three inspections of impressed current cathodic protection systems
- The results of testing from the last two inspections of cathodic protection systems performed by a qualified cathodic protection tester

6.0 Closing USTs

If a UST does not meet the performance standards for new USTs, or the upgrading requirements for existing USTs, it must be closed permanently. Procedures for properly closing a UST include:

- Notifying the implementing agency 30 days before initiating closure
- Emptying and removing the tank or filling it with inert materials
- Determining whether the system has leaked, and if so, implementing a corrective action
- Maintaining records of the results of the excavation zone assessment for the UST system for at least three years after closure

Attachment C16-1: Notification of New UST Installation

Purpose: To provide an example of notification requirements for the installation of new USTs.

Instructions: Refer to the notification form to determine potential notification requirements. This is an example of federal notification. State and/or local notifications may also be required.

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Notification for Underground Storage Tanks

State Agency Name and Address:

STATE USE ONLY

ID NUMBER:

DATE RECEIVED:

TYPE OF NOTIFICATION

☐ A. NEW FACILITY ☐ B. AMENDED ☐ C. CLOSURE

_____ No. of tanks at facility

_____ No. of continuation sheets attached

A. Date Entered into Computer _____

B. Data Entry Clerk Initials _____

C. Owner Was Contacted to Clarify Responses, Comments:

INSTRUCTIONS

Please type or print in ink all items except "signature" in section V. This form must be completed for each location containing underground storage tanks. If more than five (5) tanks are owned at this location, photocopy the following sheets, and staple continuation sheets to the form.

GENERAL INFORMATION

Notification is required by Federal law for all underground tanks that have been used to store regulated substances since January 1, 1974, that are in the ground as of May 8, 1986, or that are brought into use after May 8, 1986. The information requested is required by Section 9002 of the Resource Conservation and Recovery Act (RCRA), as amended.

The primary purpose of this notification program is to locate and evaluate underground tanks that store or have stored petroleum or hazardous substances. It is expected that the information you provide will be based on reasonably available records, or in the absence of such records, you knowledge, belief, or recollection.

Who Must Notify? Section 9002 of RCRA, as amended, requires that, unless exempted, owners of underground tanks that store regulated substances must notify designated State or local agencies of the existence of their tanks. Owner means--

(a) in the case of an underground storage tank in use on November 8, 1984, or brought into use after that date, any person who owns an underground storage tank used for storage, use, or dispensing of regulated substances, and

(b) in the case of any underground storage tank in use before November 8, 1984, but no longer in use on that date, any person who owned such tank immediately before discontinuation of its use.

(c) if the State so requires, any facility that has underground any changes to facility information or tank system status (only amended tank information needs to be included).

What Tanks Are Included? Underground storage tank is defined as any one or combination of tanks that (1) is used to contain an accumulation of "regulated substances," and (2) whose volume (including connected underground piping) is 10% or more beneath the ground. Some examples are underground tanks storing: 1. gasoline, used oil or diesel fuel, and 2. industrial solvents, pesticides, herbicides or fumigants.

What Tanks Are Excluded? Tanks removed from the ground are not subject to notification. Other tanks excluded from notification are:

1. farm or residential tanks of 1,100 gallons or less capacity used for storing motor fuel for noncommercial purposes;
2. tanks used for storing heating oil for consumptive use on the premises where stored;
3. septic tanks;
4. pipeline facilities (including gathering lines) regulated under the Natural Gas Pipeline Safety Act of 1968, or the Hazardous Liquid Pipeline Safety Act of 1979, or which is an intrastate pipeline facility regulated under State laws;
5. surface impoundments, pits, ponds, or lagoons;
6. storm water or waste water collection systems;
7. flow-through process tanks;
8. liquid traps or associated gathering lines directly related to oil or gas production and gathering operations;
9. storage tanks situated in an underground area (such as a basement, cellar, mineworking, drift, shaft, or tunnel) if the storage tank is situated upon or above the surface floor.

What Substances Are Covered? The notification requirements apply to underground storage tanks that contain regulated substances. This includes any substance defined as hazardous in Section 101 (14) of the Comprehensive Environmental Response, Compensation and Liability Act of 1980 (CERCLA), with the exception of those substances regulated as hazardous waste under Subtitle C of RCRA. It also includes petroleum, e.g., crude oil or any fraction thereof which is liquid at standard conditions of temperature and pressure (60 degrees Fahrenheit and 14.7 pounds per square inch absolute).

Where To Notify? Send completed forms to:

When To Notify? 1. Owners of underground storage tanks in use or that have been taken out of operation after January 1, 1974, but still in the ground, must notify by May 8, 1986. 2. Owners who bring underground storage tanks into use after May 8, 1986, must notify within 30 days of bringing the tanks into use. 3. If the State requires notification of any amendments to facility, send information to State agency immediately.

Penalties: Any owner who knowingly fails to notify or submits false information shall be subject to a civil penalty not to exceed $10,000 for each tank for which notification is not given or for which false information is submitted.

I. OWNERSHIP OF TANK(S)

Owner Name (Corporation, Individual, Public Agency, or Other Entity)

Street Address

City | State | Zip Code

County

Phone Number (include Area Code)

II. LOCATION OF TANK(S)

If required by State, give the geographic location of tanks by degrees, minutes, and seconds. Examples Lat. 42, 36, 12 N Long. 85, 24, 17 W

Latitude _____ **Longitude** _____

Facility Name of Company Site Identifier, as applicable | (if same as Section I, mark box here) ☐

Street Address

City | State | Zip Code

County | Municipality

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III. TYPE OF OWNER

- ☐ Federal Government
- ☐ State Government
- ☐ Local Government
- ☐ Commercial
- ☐ Private

IV. INDIAN LANDS

Tanks are located on land within an Indian Reservation or on other trust lands. ☐

Tanks are owned by native American nation, tribe, or individual ☐

Tribe or Nation:

V. TYPE OF FACILITY

- ☐ Gas Station
- ☐ Petroleum Distributor
- ☐ Air Taxi (Airline)
- ☐ Aircraft Owner
- ☐ Auto Dealership
- ☐ Railroad
- ☐ Federal - Non-Military
- ☐ Federal - Military
- ☐ Industrial
- ☐ Contractor
- ☐ Trucking/Transport
- ☐ Utilities
- ☐ Residential
- ☐ Farm
- ☐ Other (Explain) _____

VI. CONTACT PERSON IN CHARGE OF TANKS

Name:	Job Title:	Address:	Phone Number (Include Area Code):

VII. FINANCIAL RESPONSIBILITY

☐ I have met the financial responsibility requirements in accordance with 40 CFR Subpart H

Check All that Apply

- ☐ Self Insurance
- ☐ Commercial Insurance
- ☐ Risk Retention Group
- ☐ Guarantee
- ☐ Surety Bond
- ☐ Letter of Credit
- ☐ State Funds
- ☐ Trust Fund
- ☐ Other Method Allowed - Specify _____

VIII. CERTIFICATION (Read and sign after completing allsection)

I certify under penalty of law that I have personally examined and am familiar with the information submitted in this and allttached documents, and that based on my inquiry of those individuals immediately responsible for obtaining the information, I believe that the submitted information is true,ccurate, and complete.

Name and official title of owner or owner's authorized representative (Print)	Signature	Date Signed

Paperwork Reduction Act Notice

EPA estimates public reporting burden for this form to average 30 minutes per response including time for reviewing instructiogathering and maintaining the data needed and completing and reviewing the form. Send comments regarding this burden estimate to Chief, Information Policy Branch (2136)J.S. Environmental Protection Agency, 401 M Street, Washington D.C. 20460, marked "Attention Desk Officer for EPA." This form amends the previous notification formsaprinted in 40 CFR Part 280, Appendix I. Previous editions of this notification form may be used while supplies last.

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IX. DESCRIPTION OF UNDERGROUND STORAGE TANKS (Complete for each tank at this location.)

Tank Identification Number	Tank No. _____	Tank No. _____	Tank No. _____	Tank No. _____	Tank No. _____
1. Status of Tank (mark only one)					
Currently In Use	☐	☐	☐	☐	☐
Temporarily Out of Use	☐	☐	☐	☐	☐
Permanently Out of Use	☐	☐	☐	☐	☐
Amendment of Information	☐	☐	☐	☐	☐
2. Date of Installation (mo./year)					
3. Estimated Total Capacity (gallons)					
4. Material of Construction (mark all that apply)					
Asphalt Coated or Bare Steel	☐	☐	☐	☐	☐
Cathodically Protected Steel	☐	☐	☐	☐	☐
Epoxy Coated Steel	☐	☐	☐	☐	☐
Composite (Steel with Fiberglass)	☐	☐	☐	☐	☐
Fiberglass Reinforced Plastic	☐	☐	☐	☐	☐
Lined Interior	☐	☐	☐	☐	☐
Double Walled	☐	☐	☐	☐	☐
Polyethylene Tank Jacket	☐	☐	☐	☐	☐
Concrete	☐	☐	☐	☐	☐
Excavation Liner	☐	☐	☐	☐	☐
Unknown	☐	☐	☐	☐	☐
Other, Please specify	_____	_____	_____	_____	_____
	_____	_____	_____	_____	_____
Has tank been repaired?	☐	☐	☐	☐	☐
5. Piping (Material) (mark all that apply)					
Bare Steel	☐	☐	☐	☐	☐
Galvanized Steel	☐	☐	☐	☐	☐
Fiberglass Reinforced Plastic	☐	☐	☐	☐	☐
Copper	☐	☐	☐	☐	☐
Cathodically Protected	☐	☐	☐	☐	☐
Double Walled	☐	☐	☐	☐	☐
Secondary Containment	☐	☐	☐	☐	☐
Unknown	☐	☐	☐	☐	☐
Other, Please Specify	☐	☐	☐	☐	☐
6. Piping (Type) (mark all that apply)					
Suction: no valve at tank	☐	☐	☐	☐	☐
Suction: valve at tank	☐	☐	☐	☐	☐
Pressure	☐	☐	☐	☐	☐
Gravity Feed	☐	☐	☐	☐	☐
Has piping been repaired?	☐	☐	☐	☐	☐

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Tank Identification Number	Tank No. ____	Tank No. ____	Tank No. ____	Tank No. ____	Tank No. ____
7. Substance Currently or Last Stored in Greatest Quantity by Volume					
Gasoline	☐	☐	☐	☐	☐
Diesel	☐	☐	☐	☐	☐
Gasohol	☐	☐	☐	☐	☐
Kerosene	☐	☐	☐	☐	☐
Heating Oil	☐	☐	☐	☐	☐
Used Oil	☐	☐	☐	☐	☐
Other	☐	☐	☐	☐	☐
Please Specify					
Hazardous Substance	☐	☐	☐	☐	☐
CERCLA name and/or					
CAS number					
Mixture of Substances	☐	☐	☐	☐	☐
Please Specify					

X. TANKS OUT OF USE, OR CHANGE IN SERVICE

1. Closing of Tank					
A. Estimated date last used (mo./day/year)					
B. Estimated date tank closed (mo./day/year)					
C. Tank was removed from ground	☐	☐	☐	☐	☐
D. Tank was closed in ground	☐	☐	☐	☐	☐
E. Tank filled with inert material	☐	☐	☐	☐	☐
Describe					
F. Change in service	☐	☐	☐	☐	☐
2. Site Assessment Completed	☐	☐	☐	☐	☐
Evidence of a leak detected	☐	☐	☐	☐	☐

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Notification for Underground Storage Tanks

XI. CERTIFICATION OF COMPLIANCE (COMPLETE FOR ALL NEW AND UPGRADED TANKS AT THIS LOCATION)

Tank Identification Number	Tank No. _____	Tank No. _____	Tank No. _____	Tank No. _____	Tank No. _____
1. Installation					
A. Installer certified by tank and piping manufacturers	☐	☐	☐	☐	☐
B. Installer certified or licensed by the implementing agency	☐	☐	☐	☐	☐
C. Installation inspected by a registered engineer	☐	☐	☐	☐	☐
D. Installation inspected and approved by implementing agency	☐	☐	☐	☐	☐
E. Manufacturer's installation checklists have been completed	☐	☐	☐	☐	☐
F. Another method allowed by State agency. Please specify.	☐	☐	☐	☐	☐

2. Release Detection (Mark all that apply)	TANK	PIPING	TANK	PIPING	TANK	PIPING	TANK	PIPING	TANK	PIPING
A. Manual tank gauging	☐		☐		☐		☐		☐	
B. Tank tightness testing	☐		☐		☐		☐		☐	
C. Inventory Controls	☐		☐		☐		☐		☐	
D. Automatic tank gauging	☐		☐		☐		☐		☐	
E. Vapor monitoring	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
F. Groundwater monitoring	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
G. Verify monitoring/secondary containment	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
H. Automatic line leak detectors	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
I. Line tightness testing	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
J. Other method allowed by implementing agency.	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Please specify										

3. Spill and Overfill Protection					
A. Overfill device installed	☐	☐	☐	☐	☐
B. Spill device installed	☐	☐	☐	☐	☐

OATH: I certify the information concerning installation that is provided in section XI is true to the best of my belief and knowledge.

Installer: _____ (Name) _____ (Signature) _____ (Date)

_____ (Position) _____ (Company)